

FOOD AND DRUG ADMINISTRATION

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CENTER FOR DEVICES AND RADIOLOGICAL HEALTH MEDICAL

DEVICES ADVISORY COMMITTEE

+ + + + +

MEETING OF THE DENTAL PRODUCTS PANEL

+ + + + +

WEDNESDAY,

OCTOBER 12, 2005

+ + + + +

The meeting convened in the Ballroom
Salons A and B of the Hilton Washington D.C. North,
620 Perry Parkway, Gaithersburg, Maryland, at 8:07
a.m., pursuant to notice, Jon B. Suzuki, D.D.S.,
Ph.D., MBA, Chair, presiding.

COMMITTEE MEMBERS PRESENT:

JON B. SUZUKI, D.D.S., Ph.D., MBA, Chair

MICHAEL E. ADJODHA, MchE, Executive

SALOMON AMAR, D.D.S., Ph.D., Voting Member

LEIF K. BAKLAND, D.D.S., Consultant

DAVID L. COCHRAN, D.D.S., Voting Member

B. GAIL DEMKO, D.M.D., Consultant

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ELIZABETH S. HOWE, Non-Voting Member, Consumer Rep.

WILLIAM J. O'BRIEN, M.S., Ph.D., Voting Member

DANIEL R. SCHECHTER, J.D., Non-Voting Member, Consumer
Rep.

DOMENICK T. ZERO, D.D.S., M.S., Voting Member

JOHN R. ZUNIGA, Ph.D., D.M.D., Voting Member

CHIU S. LIN, Ph.D., FDA

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P R O C E E D I N G S

(8:07 a.m.)

CHAIRPERSON SUZUKI: The meeting of the
Dental Products Panel will come to order.

The first item on our agenda this morning
is root canal cleansers, and I'd like to present Ms.
Myra Browne.

MS. BROWNE: Good morning. I'm Myra
Browne, and this morning we are seeking the panel's
recommendation to classify root canal cleansers.

My presentation will include a device
description, regulatory history, medical device
reports, risk to health and mitigation, and FDA's
classification proposal for root canal cleansers.

Root canal cleansers are substances
introduced directly into the root canal in order to
clean and lubricate the root canal during endodontic
treatment. Successful root canal treatment results in
removal of the smear layer, debris, calcifications,
and possibly reduces microbial contaminants.

Root canal cleansers are pre-amendment
devices. Since 1976, these devices have been

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1 regulated as unclassified devices and are cleared
2 through the 510(k) premarket notification process.
3 Root canal cleansers contain different active
4 ingredients to achieve optimum results. These
5 ingredients may include EDTA, carbamide peroxide, and
6 quaternary ammonium compounds.

7 We have cleared one root canal cleanser
8 that contains the antimicrobial agent doxycycline.
9 Consultation with the Center for Drugs was completed
10 for this application.

11 Root canal cleansers are regulated by the
12 premarket notification process. To date, FDA has
13 cleared 14 root canal cleanser 510(k)s.

14 A search of the FDA medical device report
15 database brought up no accuracy events for root canal
16 cleansers. This table identifies the risk to health
17 associated with root canal cleansers and FDA's
18 proposed mitigations for addressing these risks. The
19 risk to health associated with root canal cleansers
20 are adverse tissue reaction to any components of the
21 cleanser, improper use of the device, and device
22 failure.

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1 The proposed mitigation is a special
2 controls guidance document which will include
3 prescription use, device labeling, chemical
4 characterization, biocompatibility testing, and
5 preclinical testing.

6 In addition, a consultation with the
7 Center for Drug Evaluation and Research may be
8 required. Voluntary standards, such as ISO 10993 and
9 ISO 7405 apply to the biocompatibility of root canal
10 cleansers.

11 To conclude, FDA is proposing the
12 following classification for root canal cleansers.
13 The identification will read, "A root canal cleanser
14 is a device that is used to clean and lubricate a root
15 canal during endodontic instrumentation."

16 The classification will read Class II,
17 special controls. The special control for this device
18 would be the guidance document Class II, special
19 controls guidance document, root canal cleanser.

20 Thank you.

21 CHAIRPERSON SUZUKI: Okay. Thank you.

22 MS. BROWNE: Are there any questions?

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1 CHAIRPERSON SUZUKI: Okay. Thank you, Ms.
2 Browne.

3 Are there any questions from the panel?

4 And before I continue, I wanted to
5 indicate for the record that Dr. Solomon Amar is not
6 at the meeting today.

7 Okay. Any questions for Ms. Browne?

8 (No response.)

9 CHAIRPERSON SUZUKI: Okay. We now have
10 an open comment session concerning the proposed
11 classification of the root canal cleanser.

12 I would like to ask if there's anyone in
13 the audience who wishes to address the panel. Please
14 approach the microphone and identify yourself.

15 (No response.)

16 CHAIRPERSON SUZUKI: Okay. If not, I'd
17 like to next call on Ms. Shulman to read the panel to
18 complete the classification forms.

19 MS. SHULMAN: Good morning, again. We'll
20 start with the general device classification
21 questionnaire. You can please place your name, the
22 date, the generic type of device on the top of the

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1 form.

2 Okay. The first question: is the device
3 life sustaining or life supporting? If you would like
4 to go around.

5 CHAIRPERSON SUZUKI: Okay. I'd like to
6 call on the panel beginning with Dr. Cochran again.

7 DR. COCHRAN: No.

8 CHAIRPERSON SUZUKI: Dr. O'Brien.

9 DR. O'BRIEN: No.

10 CHAIRPERSON SUZUKI: Dr. Zero?

11 DR. ZERO: No.

12 CHAIRPERSON SUZUKI: Dr. Zuniga.

13 DR. ZUNIGA: No.

14 CHAIRPERSON SUZUKI: And the
15 representatives, Ms. Howe.

16 MS. HOWE: No.

17 CHAIRPERSON SUZUKI: Mr. Schechter.

18 MR. SCHECHTER: No.

19 CHAIRPERSON SUZUKI: Dr. Bakland.

20 DR. BAKLAND: No.

21 CHAIRPERSON SUZUKI: And Dr. Demko.

22 DR. DEMKO: No.

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1 CHAIRPERSON SUZUKI: Okay. Unanimously no
2 for Question 1.

3 MS. SHULMAN: Thank you.

4 Question 2, is the device for use which is
5 of substantial importance in preventing impairment of
6 human health?

7 CHAIRPERSON SUZUKI: Going around the
8 panel again, Dr. Cochran.

9 DR. COCHRAN: No.

10 CHAIRPERSON SUZUKI: Dr. O'Brien.

11 DR. O'BRIEN: No.

12 CHAIRPERSON SUZUKI: Dr. Zero.

13 DR. ZERO: No.

14 CHAIRPERSON SUZUKI: Dr. Zuniga.

15 DR. ZUNIGA: No.

16 CHAIRPERSON SUZUKI: The representatives,
17 Ms. Howe.

18 MS. HOWE: No.

19 CHAIRPERSON SUZUKI: Mr. Schechter.

20 MR. SCHECHTER: No.

21 CHAIRPERSON SUZUKI: Consultants, Dr.
22 Bakland.

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1 DR. BAKLAND: No.

2 CHAIRPERSON SUZUKI: Dr. Demko.

3 DR. DEMKO: No.

4 CHAIRPERSON SUZUKI: Okay. Unanimously
5 no.

6 MS. SHULMAN: Thank you.

7 Number 3: does the device present a
8 potential unreasonable risk of illness or injury?

9 CHAIRPERSON SUZUKI: Okay. Again, Dr.
10 Cochran?

11 DR. COCHRAN: No.

12 CHAIRPERSON SUZUKI: Dr. O'Brien.

13 DR. O'BRIEN: No.

14 CHAIRPERSON SUZUKI: Dr. Zero.

15 DR. ZERO: No.

16 CHAIRPERSON SUZUKI: Dr. Zuniga.

17 DR. ZUNIGA: No.

18 CHAIRPERSON SUZUKI: The representatives,
19 Ms. Howe.

20 MS. HOWE: No.

21 CHAIRPERSON SUZUKI: Mr. Schechter.

22 MR. SCHECHTER: No.

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1 CHAIRPERSON SUZUKI: Consultants, Dr.
2 Bakland.

3 DR. BAKLAND: No.

4 CHAIRPERSON SUZUKI: Dr. Demko.

5 DR. DEMKO: No.

6 CHAIRPERSON SUZUKI: Okay. Unanimously
7 no.

8 MS. SHULMAN: Thank you.

9 Four, did you answer yes to any of the
10 above three questions? The answer is no. We go to
11 number five. Is there sufficient information to
12 determine that general controls -- those are the
13 Class I -- are sufficient to provide reasonable
14 assurance of safety and effectiveness?

15 CHAIRPERSON SUZUKI: Okay. Dr. Cochran?

16 DR. COCHRAN: No.

17 CHAIRPERSON SUZUKI: Dr. O'Brien.

18 DR. O'BRIEN: No.

19 CHAIRPERSON SUZUKI: Dr. Zero.

20 DR. ZERO: No.

21 CHAIRPERSON SUZUKI: Dr. Zuniga.

22 DR. ZUNIGA: No.

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1 CHAIRPERSON SUZUKI: The representatives,
2 Ms. Howe.

3 MS. HOWE: No.

4 CHAIRPERSON SUZUKI: Mr. Schechter.

5 MR. SCHECHTER: No.

6 CHAIRPERSON SUZUKI: Dr. Bakland.

7 DR. BAKLAND: No.

8 CHAIRPERSON SUZUKI: Dr. Demko.

9 DR. DEMKO: No.

10 CHAIRPERSON SUZUKI: Okay. Unanimously
11 no.

12 MS. SHULMAN: Thank you.

13 Number 6: is there sufficient information
14 to establish special controls in addition to general
15 controls to provide reasonable assurance of safety and
16 effectiveness?

17 CHAIRPERSON SUZUKI: Dr. Cochran?

18 DR. COCHRAN: Yes.

19 CHAIRPERSON SUZUKI: Dr. O'Brien.

20 DR. O'BRIEN: Yes.

21 CHAIRPERSON SUZUKI: Dr. Zero.

22 DR. ZERO: Yes.

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1 CHAIRPERSON SUZUKI: Dr. Zuniga.

2 DR. ZUNIGA: Yes.

3 CHAIRPERSON SUZUKI: Ms. Howe.

4 MS. HOWE: Yes.

5 CHAIRPERSON SUZUKI: Mr. Schechter.

6 MR. SCHECHTER: Yes.

7 CHAIRPERSON SUZUKI: Dr. Bakland.

8 DR. BAKLAND: Yes.

9 CHAIRPERSON SUZUKI: Dr. Demko.

10 DR. DEMKO: Yes.

11 CHAIRPERSON SUZUKI: Unanimously yes.

12 MS. SHULMAN: Thank you.

13 Number 7, if there is sufficient
14 information to establish special controls to provide
15 reasonable assurance of safety and effectiveness,
16 identify the special controls needed to provide such
17 reasonable assurance for the Class II. Again, it can
18 be any on the sheet or any others.

19 CHAIRPERSON SUZUKI: I'll begin with Dr.
20 Cochran.

21 DR. COCHRAN: The guidance document.

22 CHAIRPERSON SUZUKI: Dr. O'Brien?

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1 DR. O'BRIEN: The guidance document.

2 CHAIRPERSON SUZUKI: Dr. Zero.

3 DR. ZERO: Guidance.

4 CHAIRPERSON SUZUKI: Dr. Zuniga.

5 DR. ZUNIGA: Guidance document.

6 CHAIRPERSON SUZUKI: Representatives, Ms.

7 Howe.

8 MS. HOWE: Guidance document.

9 CHAIRPERSON SUZUKI: Mr. Schechter.

10 MR. SCHECHTER: Guidance document.

11 CHAIRPERSON SUZUKI: Dr. Bakland.

12 DR. BAKLAND: Guidance documents.

13 CHAIRPERSON SUZUKI: Dr. Demko.

14 DR. DEMKO: Guidance document.

15 CHAIRPERSON SUZUKI: Unanimously guidance
16 document.

17 MS. SHULMAN: Thank you.

18 Okay. Again, number eight and nine we may
19 skip because that only has to do with performance
20 standards, and Question 10 only has to do with Class
21 III devices.

22 CHAIRPERSON SUZUKI: Okay. Low, medium or

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1 high.

2 Dr. Cochran.

3 DR. COCHRAN: Low.

4 CHAIRPERSON SUZUKI: Okay. Dr. O'Brien.

5 DR. O'BRIEN: Low.

6 CHAIRPERSON SUZUKI: Dr. Zero.

7 DR. ZERO: Low.

8 CHAIRPERSON SUZUKI: Dr. Zuniga.

9 DR. ZUNIGA: Low.

10 CHAIRPERSON SUZUKI: Representatives, Ms.

11 Howe.

12 MS. HOWE: Low.

13 CHAIRPERSON SUZUKI: Mr. Schechter.

14 PARTICIPANT: We don't need to do this.

15 MS. SHULMAN: We're moving to Question 11

16 now. Question 11 is the prescription statement again,

17 and again, these were prescription devices pre-

18 amendment. So the first one would apply. If there's

19 anything else you'd like to add at this time you can

20 let us know.

21 CHAIRPERSON SUZUKI: Okay. The needed

22 restrictions. Dr. Cochran.

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1 DR. COCHRAN: First box.

2 CHAIRPERSON SUZUKI: Okay. Dr. O'Brien.

3 DR. O'BRIEN: First box.

4 CHAIRPERSON SUZUKI: Dr. Zero.

5 DR. ZERO: First box.

6 CHAIRPERSON SUZUKI: Dr. Zuniga.

7 DR. ZUNIGA: First box.

8 CHAIRPERSON SUZUKI: Ms. Howe.

9 MS. HOWE: First box.

10 CHAIRPERSON SUZUKI: Mr. Schechter.

11 MR. SCHECHTER: First box.

12 CHAIRPERSON SUZUKI: Dr. Bakland.

13 DR. BAKLAND: First box.

14 CHAIRPERSON SUZUKI: Dr. Demko.

15 DR. DEMKO: First box.

16 CHAIRPERSON SUZUKI: Unanimously first

17 box.

18 MS. SHULMAN: Thank you.

19 Okay. We can move on to the supplemental

20 data sheet. Again, if you can place your name on the

21 top, the generic type of device, the advisory panel,

22 and is the device an implant? The answer is no.

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1 Question 4, the indications for use was
2 presented by Ms. Browne. It's up on the screen now.
3 If there's any comments or you can put "as presented
4 during the panel meeting."

5 CHAIRPERSON SUZUKI: Any comments,
6 questions on number four?

7 (No response.)

8 CHAIRPERSON SUZUKI: Okay.

9 MS. SHULMAN: Thank you.

10 We can move on to number five, the
11 identification of the risks, again, are up on the
12 screen as presented during the panel meeting. If
13 there's no additions you can put as presented during
14 the panel meeting.

15 CHAIRPERSON SUZUKI: Any comments,
16 questions on number five?

17 (No response.)

18 MS. SHULMAN: Thank you.

19 Number six, the recommended advisory
20 classification is Class II and the priority, again, is
21 high, medium or low.

22 CHAIRPERSON SUZUKI: Okay. Any questions

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1 on this before I go through priorities?

2 (No response.)

3 CHAIRPERSON SUZUKI: Okay. Beginning with
4 Dr. Cochran.

5 CHAIRPERSON SUZUKI: Okay. Dr. O'Brien.

6 DR. O'BRIEN: Low.

7 CHAIRPERSON SUZUKI: Dr. Zero.

8 DR. ZERO: Low.

9 CHAIRPERSON SUZUKI: Dr. Zuniga.

10 DR. ZUNIGA: Low.

11 CHAIRPERSON SUZUKI: Ms. Howe.

12 MS. HOWE: Low.

13 CHAIRPERSON SUZUKI: Mr. Schechter.

14 MR. SCHECHTER: Low.

15 CHAIRPERSON SUZUKI: Dr. Bakland.

16 DR. BAKLAND: Low.

17 CHAIRPERSON SUZUKI: Dr. Demko.

18 DR. DEMKO: Low.

19 CHAIRPERSON SUZUKI: Okay. Unanimously
20 low.

21 MS. SHULMAN: Thank you.

22 Number seven we may skip because it's not

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1 an implant or life sustaining or life supporting.

2 And number eight, the summary of clinical
3 information, information including clinical experience
4 or judgment upon which the classification
5 recommendation is based you may say is presented
6 during the panel meeting or add anything else at this
7 time.

8 CHAIRPERSON SUZUKI: Any comments or
9 questions on number eight from the panel?

10 (No response.)

11 CHAIRPERSON SUZUKI: Okay.

12 MS. SHULMAN: Thank you.

13 Number nine, identification of any needed
14 restrictions on the use of the device, for example,
15 special labeling, besides the prescription use
16 statement we already have.

17 CHAIRPERSON SUZUKI: Okay. Any questions,
18 comments on number nine?

19 (No response.)

20 CHAIRPERSON SUZUKI: Okay.

21 MS. SHULMAN: Thank you.

22 Number ten we may skip because that only

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1 has to do with Class 1 devices.

2 Number 11, would you recommend it to be
3 exempt from premarket notification?

4 CHAIRPERSON SUZUKI: Okay. Any questions
5 before we go around the panel?

6 (No response.)

7 CHAIRPERSON SUZUKI: Okay. Dr. Cochran.

8 DR. COCHRAN: Nonexempt.

9 CHAIRPERSON SUZUKI: Dr. O'Brien.

10 DR. O'BRIEN: Nonexempt.

11 CHAIRPERSON SUZUKI: Dr. Zero.

12 DR. ZERO: Nonexempt.

13 CHAIRPERSON SUZUKI: Dr. Zuniga.

14 DR. ZUNIGA: Nonexempt.

15 CHAIRPERSON SUZUKI: Representatives, Ms.

16 Howe.

17 MS. HOWE: Not exempt.

18 CHAIRPERSON SUZUKI: Mr. Schechter.

19 MR. SCHECHTER: Not exempt.

20 CHAIRPERSON SUZUKI: Dr. Bakland.

21 DR. BAKLAND: Nonexempt.

22 CHAIRPERSON SUZUKI: Dr. Demko.

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1 DR. DEMKO: Not exempt.

2 CHAIRPERSON SUZUKI: Unanimously
3 nonexempt.

4 MS. SHULMAN: Thank you.

5 Number 12, any other existing standards
6 besides the ones that are presented that you'd like to
7 add at this time?

8 CHAIRPERSON SUZUKI: Okay. Questions or
9 comments on number 12?

10 (No response.)

11 CHAIRPERSON SUZUKI: Okay.

12 MS. SHULMAN: Okay. Thank you.

13 Now, if you'd please like to vote on the
14 forms as filled out as a Class II device requiring
15 premarket notification subject to the special controls
16 guidance document.

17 CHAIRPERSON SUZUKI: I'll ask if you're in
18 favor or opposed to our supplemental.

19 Dr. Cochran.

20 DR. COCHRAN: In favor.

21 CHAIRPERSON SUZUKI: Dr. O'Brien.

22 DR. O'BRIEN: In favor.

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1 CHAIRPERSON SUZUKI: Dr. Zero.

2 DR. ZERO: In favor.

3 CHAIRPERSON SUZUKI: Dr. Zuniga.

4 DR. ZUNIGA: In favor.

5 CHAIRPERSON SUZUKI: Representatives, Ms.

6 Howe.

7 MS. HOWE: In favor.

8 CHAIRPERSON SUZUKI: Mr. Schechter.

9 MR. SCHECHTER: In favor.

10 CHAIRPERSON SUZUKI: Dr. Bakland.

11 DR. BAKLAND: In favor.

12 CHAIRPERSON SUZUKI: Dr. Demko.

13 DR. DEMKO: In favor.

14 CHAIRPERSON SUZUKI: Unanimously in favor.

15 MS. SHULMAN: Thank you.

16 CHAIRPERSON SUZUKI: I'm going to skip the

17 break and we'll continue with the next presentation on

18 root apex locators. Mr. Michael Ryan.

19 MR. RYAN: Good morning. I'm Michael

20 Ryan, and I'll be presenting on the classification of

21 root apex locators.

22 The presentation will follow the order

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1 laid out on this slide. We'll go through a brief
2 description and regulatory history of these devices,
3 medical device reports, risks to health, and possible
4 mitigations, and the FDA proposal.

5 Root apex locators are intended to measure
6 the working length of a patient's root canal by
7 finding the apical form in the vat canal. This
8 procedure is adjunctive to other endodontic
9 procedures.

10 Root apex locators consist of a power
11 source, a lip clip electrode, a root canal probe, and
12 a display unit. They operate by employing a small
13 voltage current. The liquid is hooked to the side of
14 a patient's mouth and the root canal probe, a piece
15 that is similar to an endodontic file, is placed in
16 the patient's root canal. The power source applies
17 the current, and patients oral tissue forms a complete
18 circuit. The location device measures the impedance
19 between the lip and the probe and the impedance
20 between the lip and the apex is a know value. So as
21 the probe moves through the canal different impedance
22 values are measured and displayed as root canal

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1 positions.

2 The voltage supplied by the device differs
3 between models as does the display.

4 More recent innovations include different
5 displays such as the one shown here, and they're used
6 in attempts to improve ease of use. Instead of metal
7 root canal probes and devices integrated holders that
8 could just grasp a typical endodontic file, many
9 attempts to increase accuracy have been made. Probes
10 were insulated with plastic coatings in an attempt to
11 resist interference from oral electrolytes, like blood
12 or saliva. Original devices usually employ the direct
13 current. Newer devices found that AC current was more
14 reliable.

15 Some devices use multiple frequencies to
16 measure impedances. This was based on findings that
17 the ratio between impedances measured at different
18 frequencies is a more reliable value than an impedance
19 measured at one frequency.

20 These devices have been on the market
21 since prior to 1976. They have been regulated
22 unclassified devices due to 510(k). The earliest

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1 submission was received in 1986, and 18 510(k)s have
2 been cleared to date.

3 A search of the medical device report
4 database showed no adverse event reports for root apex
5 locators.

6 The most apparent risk to health for these
7 devices are electrical in nature. The most obvious of
8 those is electrical shock. Any time a patient and/or
9 a user is exposed to current, someone getting shocked
10 is a possibility. This risk can be mitigated by
11 insuring that the devices are designed according to
12 appropriate specifications that will keep the voltage
13 and current below dangerous levels.

14 In addition, preclinical electrical safety
15 testing should be provided in order to show that
16 electrical shock will not be a problem. This testing
17 will take into consideration not just the voltage or
18 current levels, but the design of the device.

19 Compliance with voluntary standards, such
20 as IEC 60601, is an example of one way in which a
21 manufacturer might satisfy necessary testing and
22 demonstrate electrical safety.

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1 Finally, labeling can be used to provide
2 warnings that will lessen the risk of electrical
3 shock. Language instructing the user not to attempt
4 certain repairs of the device would be useful.

5 Another important consideration with
6 dealing with electronic devices is electromagnetic
7 interference. Again, compliance with IEC 60601 would
8 mitigate this risk.

9 Other risks include cross-contamination,
10 which is an issue due to the fact that this device is
11 reusable. Any parts that contact the patient require
12 sterilization or replacement between patients.
13 Labeling should instruct the user to properly
14 sterilize the device. Any sterilization protocol
15 needs to be validated according to voluntary
16 standards, such as ISO 11134.

17 Adverse tissue reaction to patient contact
18 with materials is another possible risk. To avoid
19 this risk, biocompatibility will have to be insured.
20 Relevant biocompatibility standards, such as ISO 10993
21 and ISO 7405 are appropriate.

22 Improper use is also a consideration.

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1 Improper use could lead to patient pain, tissue
2 damage, or inaccurate readings. Good labeling and a
3 restriction to prescription use only should mitigate
4 this.

5 Device failure is a remote risk which
6 could lead to inaccurate readings. Accuracy testing
7 will mitigate this.

8 Finally, FDA would like to propose the
9 following. The identification, the root apex locator
10 is an electronic device intended to measure the
11 working length of a root canal. This would be a Class
12 II special controls device, and special control would
13 be the guidance document, Class II, special controls
14 guidance document, root apex locators.

15 Thank you.

16 CHAIRPERSON SUZUKI: Thank you.

17 I'd like to ask the panel if they have any
18 questions on the presentation to Mr. Ryan. Dr.
19 O'Brien.

20 DR. O'BRIEN: Yes. Which voltage ranges
21 do these operate in?

22 MR. RYAN: I don't have a specific range

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1 to give you, but it's very low.

2 DR. O'BRIEN: It's low. So do any of them
3 employ batteries instead of direct connection with
4 power?

5 MR. RYAN: Yes, the power source is
6 usually a rechargeable battery. It's not usually
7 connected to the wall itself.

8 DR. O'BRIEN: Another question. Have
9 there been studies on the accuracy of the root canal
10 depths as compared to actually sectioning the teeth?

11 MR. RYAN: Accuracy testing usually
12 consists of either measuring -- the manufacturer
13 either measures their device against radio -- just X-
14 rays or they measure it against another device that's
15 already on the market, and they usually do this in a
16 critical study of, you know, small number of patients.

17 DR. O'BRIEN: What's the range of
18 accuracy?

19 MR. RYAN: Oh, the range of accuracy is
20 usually within half a millimeter.

21 DR. O'BRIEN: Okay. So they're quite
22 accurate then.

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1 MR. RYAN: Yes.

2 DR. O'BRIEN: Okay.

3 CHAIRPERSON SUZUKI: Other questions,
4 comments? Dr. Bakland.

5 DR. BAKLAND: Just a comment on that.
6 Actually there have been a number of studies, you
7 know, comparing the actual length using teeth, and the
8 current consensus is that properly done, electronic
9 apex locators are even more accurate than radiographs.

10 CHAIRPERSON SUZUKI: Thank you.

11 Questions, comments? Dr. Zuniga.

12 DR. ZUNIGA: Does the electromagnetic
13 proposed mitigation cover or would it determine if
14 there's any interference with pacemaker and other
15 implantable electrical devices?

16 MR. RYAN: Well, that would most likely
17 have to be part of the labeling. You know, use it --
18 do not use it when the user or the patient has a
19 pacemaker.

20 CHAIRPERSON SUZUKI: Okay. Other
21 comments, questions?

22 (No response.)

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1 CHAIRPERSON SUZUKI: Okay. We now have an
2 open comment session concerning the proposed
3 classification of the root apex locator. If there's
4 anyone in the audience who wishes to address the
5 panel, please approach the microphone and identify
6 yourself for the record.

7 (No response.)

8 CHAIRPERSON SUZUKI: If none, I'd like to
9 call again on Ms. Shulman to lead the panel to
10 complete the classification.

11 MS. SHULMAN: Okay. Thank you.

12 Again, if you can place your names on the
13 sheet, the date, the generic type of device on the top
14 of the form, and we will start with Question 1. Is
15 the device life sustaining or life supporting?

16 CHAIRPERSON SUZUKI: Okay. Beginning with
17 Dr. Cochran.

18 DR. COCHRAN: No.

19 CHAIRPERSON SUZUKI: Dr. O'Brien.

20 DR. O'BRIEN: No.

21 CHAIRPERSON SUZUKI: Dr. Zero?

22 DR. ZERO: No.

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1 CHAIRPERSON SUZUKI: Dr. Zuniga.

2 DR. ZUNIGA: No.

3 CHAIRPERSON SUZUKI: And the
4 representatives, Ms. Howe.

5 MS. HOWE: No.

6 CHAIRPERSON SUZUKI: Mr. Schechter.

7 MR. SCHECHTER: No.

8 CHAIRPERSON SUZUKI: Dr. Bakland.

9 DR. BAKLAND: No.

10 CHAIRPERSON SUZUKI: And Dr. Demko.

11 DR. DEMKO: No.

12 CHAIRPERSON SUZUKI: Okay. Unanimously
13 no.

14 MS. SHULMAN: Thank you.

15 Number two, is the device for use which is
16 of substantial importance in preventing impairment of
17 human health?

18 CHAIRPERSON SUZUKI: Again polling the
19 panel, Dr. Cochran.

20 DR. COCHRAN: No.

21 CHAIRPERSON SUZUKI: Dr. O'Brien.

22 DR. O'BRIEN: No.

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1 CHAIRPERSON SUZUKI: Dr. Zero.

2 DR. ZERO: No.

3 CHAIRPERSON SUZUKI: Dr. Zuniga.

4 DR. ZUNIGA: No.

5 CHAIRPERSON SUZUKI: Ms. Howe.

6 MS. HOWE: No.

7 CHAIRPERSON SUZUKI: Mr. Schechter.

8 MR. SCHECHTER: No.

9 CHAIRPERSON SUZUKI: Dr. Bakland.

10 DR. BAKLAND: No.

11 CHAIRPERSON SUZUKI: Dr. Demko.

12 DR. DEMKO: No.

13 CHAIRPERSON SUZUKI: Okay. Unanimously
14 no.

15 MS. SHULMAN: Thank you.

16 Question 3: does the device present a
17 potential unreasonable risk of illness or injury?

18 CHAIRPERSON SUZUKI: Okay. Beginning
19 again with Dr. Cochran.

20 DR. COCHRAN: No.

21 CHAIRPERSON SUZUKI: Dr. O'Brien.

22 DR. O'BRIEN: No.

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1 CHAIRPERSON SUZUKI: Dr. Zero.

2 DR. ZERO: No.

3 CHAIRPERSON SUZUKI: Dr. Zuniga.

4 DR. ZUNIGA: No.

5 CHAIRPERSON SUZUKI: The representatives,
6 Ms. Howe.

7 MS. HOWE: No.

8 CHAIRPERSON SUZUKI: Mr. Schechter.

9 MR. SCHECHTER: No.

10 CHAIRPERSON SUZUKI: Dr. Bakland.

11 DR. BAKLAND: No.

12 CHAIRPERSON SUZUKI: Dr. Demko.

13 DR. DEMKO: No.

14 CHAIRPERSON SUZUKI: Unanimously no.

15 MS. SHULMAN: Thank you.

16 Number four, did you answer yes to any of
17 the above three questions? The answer is no. We will
18 go to number five. Is there sufficient information to
19 determine that general controls are sufficient to
20 provide reasonable assurance of safety and
21 effectiveness?

22 CHAIRPERSON SUZUKI: Okay. Beginning

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1 again with the panel, Dr. Cochran.

2 DR. COCHRAN: No.

3 CHAIRPERSON SUZUKI: Dr. O'Brien.

4 DR. O'BRIEN: No.

5 CHAIRPERSON SUZUKI: Dr. Zero.

6 DR. ZERO: No.

7 CHAIRPERSON SUZUKI: Dr. Zuniga.

8 DR. ZUNIGA: No.

9 CHAIRPERSON SUZUKI: Ms. Howe.

10 MS. HOWE: No.

11 CHAIRPERSON SUZUKI: Mr. Schechter.

12 MR. SCHECHTER: Sine my company
13 manufactures these devices I'm sure they'd love me to
14 say yes, but I'll say no.

15 (Laughter.)

16 CHAIRPERSON SUZUKI: Dr. Bakland.

17 DR. BAKLAND: No.

18 CHAIRPERSON SUZUKI: Dr. Demko.

19 DR. DEMKO: No.

20 CHAIRPERSON SUZUKI: Okay. Unanimously
21 no.

22 MS. SHULMAN: Thank you.

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1 Number 7: if there is sufficient -- six,
2 is there sufficient information to establish special
3 controls in addition to general controls to provide
4 reasonable assurance of safety and effectiveness?

5 CHAIRPERSON SUZUKI: Okay. Beginning
6 again, Dr. Cochran.

7 DR. COCHRAN: Yes.

8 CHAIRPERSON SUZUKI: Dr. O'Brien.

9 DR. O'BRIEN: Yes.

10 CHAIRPERSON SUZUKI: Dr. Zero.

11 DR. ZERO: Yes.

12 CHAIRPERSON SUZUKI: Dr. Zuniga.

13 DR. ZUNIGA: Yes.

14 CHAIRPERSON SUZUKI: Ms. Howe.

15 MS. HOWE: Yes.

16 CHAIRPERSON SUZUKI: Mr. Schechter.

17 MR. SCHECHTER: Yes.

18 CHAIRPERSON SUZUKI: Dr. Bakland.

19 DR. BAKLAND: Yes.

20 CHAIRPERSON SUZUKI: Dr. Demko.

21 DR. DEMKO: Yes.

22 CHAIRPERSON SUZUKI: Unanimously yes.

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1 MS. SHULMAN: Thank you.

2 Number 7, if there is sufficient
3 information to establish special controls to provide
4 reasonable assurance of safety and effectiveness,
5 identify the special controls needed to provide such
6 reasonable assurance for Class II.

7 CHAIRPERSON SUZUKI: I'll begin with Dr.
8 Cochran.

9 DR. COCHRAN: The guidance document.

10 CHAIRPERSON SUZUKI: Dr. O'Brien?

11 DR. O'BRIEN: The guidance document.

12 CHAIRPERSON SUZUKI: Dr. Zero.

13 DR. ZERO: Guidance document.

14 CHAIRPERSON SUZUKI: Dr. Zuniga.

15 DR. ZUNIGA: Guidance document.

16 CHAIRPERSON SUZUKI: Representatives, Ms.
17 Howe.

18 MS. HOWE: Guidance document.

19 CHAIRPERSON SUZUKI: Mr. Schechter.

20 MR. SCHECHTER: Guidance document.

21 CHAIRPERSON SUZUKI: Dr. Bakland.

22 DR. BAKLAND: Guidance document.

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1 CHAIRPERSON SUZUKI: Dr. Demko.

2 DR. DEMKO: Guidance document.

3 CHAIRPERSON SUZUKI: Unanimously guidance
4 document.

5 MS. SHULMAN: Thank you.

6 Again, Question 8 and 9 we may skip
7 because that only has to do with performance
8 standards, and 10 only has to do with Class III
9 devices.

10 Number 11, identify the need of
11 restrictions. The first one is the prescription
12 statement. It was a prescription device, but if
13 there's anything else you'd like to add at this time.

14 CHAIRPERSON SUZUKI: Okay. Any questions
15 before we vote?

16 (No response.)

17 CHAIRPERSON SUZUKI: Dr. Cochran.

18 DR. COCHRAN: First box.

19 CHAIRPERSON SUZUKI: Okay. Dr. O'Brien.

20 DR. O'BRIEN: First box.

21 CHAIRPERSON SUZUKI: Dr. Zero.

22 DR. ZERO: First box.

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1 CHAIRPERSON SUZUKI: Dr. Zuniga.

2 DR. ZUNIGA: First box.

3 CHAIRPERSON SUZUKI: Ms. Howe.

4 MS. HOWE: First box.

5 CHAIRPERSON SUZUKI: Mr. Schechter.

6 MR. SCHECHTER: First box.

7 CHAIRPERSON SUZUKI: Dr. Bakland.

8 DR. BAKLAND: First box.

9 CHAIRPERSON SUZUKI: Dr. Demko.

10 DR. DEMKO: First box.

11 CHAIRPERSON SUZUKI: Unanimously only upon
12 written and oral authorization of the practitioner

13 MS. SHULMAN: Thank you.

14 Okay. Now we will move on to the
15 supplemental data sheet. Again, your name, the
16 generic type of device, the advisory panel, and number
17 three, is the device an implant? No.

18 Number four, the indications for use were
19 presented and they're on the screen. You can say on
20 the form "as presented" or you can add anything else
21 at this time.

22 CHAIRPERSON SUZUKI: Any questions or

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1 comments on number four?

2 (No response.)

3 CHAIRPERSON SUZUKI: Okay.

4 MS. SHULMAN: Thank you.

5 Number five, the identification of the
6 risks to health presented by the device. There were
7 two slides of this that were presented during the
8 panel meeting. You can say "as presented on the form"
9 or you can add anything else at this time.

10 CHAIRPERSON SUZUKI: Any other questions
11 or comments on number five from the panel?

12 (No response.)

13 CHAIRPERSON SUZUKI: Okay.

14 MS. SHULMAN: Thank you.

15 Number six, the recommended advisory
16 classification is Class II and the priority, again,
17 could be high, medium or low.

18 CHAIRPERSON SUZUKI: Okay. Choosing
19 either high, medium or low, Dr. Cochran?

20 DR. COCHRAN: Low.

21 CHAIRPERSON SUZUKI: Dr. O'Brien.

22 DR. O'BRIEN: Low.

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1 CHAIRPERSON SUZUKI: Dr. Zero.

2 DR. ZERO: Low.

3 CHAIRPERSON SUZUKI: Dr. Zuniga.

4 DR. ZUNIGA: Low.

5 CHAIRPERSON SUZUKI: Ms. Howe.

6 MS. HOWE: Low.

7 CHAIRPERSON SUZUKI: Mr. Schechter.

8 MR. SCHECHTER: Low.

9 CHAIRPERSON SUZUKI: Dr. Bakland.

10 DR. BAKLAND: Low.

11 CHAIRPERSON SUZUKI: Dr. Demko.

12 DR. DEMKO: Low.

13 CHAIRPERSON SUZUKI: Okay. Unanimously
14 low.

15 MS. SHULMAN: Thank you.

16 Number seven we may skip because it's not
17 an implant or life sustaining or life supporting.

18 And number eight, the summary of
19 information, including clinical experience or judgment
20 upon which the classification recommendation is based.

21 Again, you may add anything or say as presented in
22 the panel meeting.

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1 CHAIRPERSON SUZUKI: Questions or comments
2 on number eight from the panel?

3 (No response.)

4 CHAIRPERSON SUZUKI: Okay.

5 MS. SHULMAN: Thank you.

6 Number nine, identification of any needed
7 restrictions on the use of the device. We already
8 have the prescription labeling. If there's anything
9 else you'd like to add.

10 CHAIRPERSON SUZUKI: Okay. Any questions
11 or comments on number nine?

12 (No response.)

13 CHAIRPERSON SUZUKI: No.

14 MS. SHULMAN: Thank you.

15 Number ten we may skip because that's a
16 Class I question.

17 Number 11, if the device is recommended
18 for Class II, recommend whether FDA should exempt it
19 from premarket notification.

20 CHAIRPERSON SUZUKI: Okay. Either exempt
21 or nonexempt. Dr. Cochran.

22 DR. COCHRAN: Not exempt.

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1 CHAIRPERSON SUZUKI: Dr. O'Brien.

2 DR. O'BRIEN: Not exempt.

3 CHAIRPERSON SUZUKI: Dr. Zero.

4 DR. ZERO: Not exempt.

5 CHAIRPERSON SUZUKI: Dr. Zuniga.

6 DR. ZUNIGA: Not exempt.

7 CHAIRPERSON SUZUKI: Representatives, Ms.

8 Howe.

9 MS. HOWE: Not exempt.

10 CHAIRPERSON SUZUKI: Mr. Schechter.

11 MR. SCHECHTER: Not exempt.

12 CHAIRPERSON SUZUKI: Dr. Bakland.

13 DR. BAKLAND: Not exempt.

14 CHAIRPERSON SUZUKI: Dr. Demko.

15 DR. DEMKO: Not exempt.

16 CHAIRPERSON SUZUKI: Unanimously

17 nonexempt.

18 MS. SHULMAN: Thank you.

19 Number 12, any other existing standards
20 that you know of that you'd like to add?

21 CHAIRPERSON SUZUKI: Okay. Questions or
22 comments on number 12?

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1 (No response.)

2 CHAIRPERSON SUZUKI: Okay. None.

3 MS. SHULMAN: Okay. Thank you.

4 Now, if you'll please vote on the forms as
5 completed as a Class II device requiring premarket
6 notification subject to the special controls guidance
7 document.

8 CHAIRPERSON SUZUKI: Okay. The panel will
9 now vote on either in favor or opposed to the
10 document.

11 Dr. Cochran.

12 DR. COCHRAN: In favor.

13 CHAIRPERSON SUZUKI: Dr. O'Brien.

14 DR. O'BRIEN: In favor.

15 CHAIRPERSON SUZUKI: Dr. Zero.

16 DR. ZERO: In favor.

17 CHAIRPERSON SUZUKI: Dr. Zuniga.

18 DR. ZUNIGA: In favor.

19 CHAIRPERSON SUZUKI: Representatives, Ms.
20 Howe.

21 MS. HOWE: In favor.

22 CHAIRPERSON SUZUKI: Mr. Schechter.

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1 MR. SCHECHTER: In favor.

2 CHAIRPERSON SUZUKI: Dr. Bakland.

3 DR. BAKLAND: In favor.

4 CHAIRPERSON SUZUKI: Dr. Demko.

5 DR. DEMKO: In favor.

6 CHAIRPERSON SUZUKI: Unanimously in favor.

7 MS. SHULMAN: Thank you.

8 CHAIRPERSON SUZUKI: Okay. I would like
9 next to proceed with the FDA presentation on dental
10 mouthguards. Dr. Kevin Mulry, Dental Officer, will be
11 presenting.

12 Okay, Dr. Mulry.

13 DR. MULRY: Thank you.

14 Good morning. I'm Kevin Mulry, and I
15 would like to thank the panel for taking the time
16 today to discuss the proposed classification of dental
17 mouthguards.

18 This slide outlines the topics I intend to
19 discuss during my presentation. It includes dental
20 mouthguard description, recreational mouthguards,
21 bruxism, the regulatory history of dental mouthguards,
22 medical device reports, risk to health mitigations,

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1 and the FDA classification proposal.

2 A dental mouthguard is an intraoral
3 therapeutic device fabricated from hard or soft
4 acrylic that is intended for protection against tooth
5 grinding, bruxism, and jaw clenching that may be
6 associated with temporomandibular disorder syndrome or
7 orificial pain. It is also intended to provide short-
8 term pain relief for muscle spasm associated with
9 occlusal interference, and it can be associated with
10 increased muscular activity.

11 Devices labeled exclusively for protecting
12 teeth during recreational use would not be covered by
13 this classification.

14 Most of the 510(k)s for mouthguards
15 submitted to the Dental Branch have included bruxism
16 as an indication for use. So I would like to spend a
17 few minutes discussing bruxism.

18 Bruxism refers to subconscious,
19 nonfunctional grinding and clenching of the teeth. It
20 commonly occurs during sleep, but may occur during the
21 day and can play a significant role in
22 temporomandibular disorders. Mouthguards are intended

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1 for the prevention of impairment to the function of
2 the teeth, jaw or orimusculature.

3 The functional anatomy involved in bruxism
4 includes the components of the temporomandibular
5 joint, the articular surfaces, and the muscles of
6 mastication.

7 The signs and symptoms of bruxism are
8 teeth grinding or clenching, teeth that are worn or
9 chipped, increased tooth sensitivity, jaw pain,
10 chronic facial pain, and ear or jaw muscle
11 contractions.

12 Mouthguards have been individually
13 fabricated for each patient by dentist in their
14 offices since at least the 1940s. Recently these
15 products have been commercialized, and FDA has cleared
16 approximately eight 510(k)s that all prescription
17 devices.

18 There has been only one adverse event
19 reported for dental mouthguards which resulted from
20 the defective package.

21 This table identifies the risk to health
22 and proposed mitigations to address these risks. Risk

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1 to health posed by mouthguards include adverse tissue
2 reactions which may be mitigated by the use of
3 biocompatibility testing and labeling. Standards that
4 apply to biocompatibility testing of mouthguards
5 include ISO 10993 and ISO 7405.

6 The risk of device failure may be
7 demonstrated by tissue irritations or increased
8 orificial pain. Device failure may be mitigated
9 through preclinical testing of the device and proper
10 labeling.

11 Other risks to health include jaw pain,
12 tooth pain, joint noises, loosening or shifting of the
13 teeth a change in bite that lasts longer than a few
14 minutes, or improper use.

15 A mitigation for these risks is labeling,
16 which includes a specification for prescription use
17 and, therefore, assumes a competent intervention on
18 behalf of the patient. Prescription devices are
19 exempt from the requirements of adequate directions
20 for use for the layperson.

21 This slide presents the FDA proposed Code
22 of Federal Regulations identification stated as a

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1 dental mouthguard is an interoral therapeutic device
2 intended to provide protection against tooth grinding,
3 bruxism or jaw clenching that may result in orificial
4 pain.

5 The proposed classification is Class 2
6 with special controls. The special controls for this
7 device would be the special controls guidance
8 document, Class II special controls guidance document,
9 dental mouthguard.

10 Thank you, and I'd be glad to answer any
11 questions.

12 CHAIRPERSON SUZUKI: Okay. I'd like to
13 ask the panel if there are any questions on the
14 presentation. Dr. Zuniga.

15 DR. ZUNIGA: Of the 14 or -- I'm sorry --
16 eight 510(k) devices that you described, how many are
17 hard and how many are soft acrylic?

18 DR. MULRY: Probably evenly divided.

19 CHAIRPERSON SUZUKI: Dr. Demko.

20 DR. DEMKO: My question is how many are
21 available only through a dentist, and are any of them
22 over the counter at this point?

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1 DR. MULRY: To date all over-the-counter
2 dental mouthguards are medical devices and are
3 prescription only devices.

4 CHAIRPERSON SUZUKI: Dr. Zuniga.

5 DR. ZUNIGA: Do the devices have an
6 expiration date on them? In other words, are they
7 intended to be used for a short time, long time, or is
8 there any indication on any of the devices?

9 DR. MULRY: We have not had any expiration
10 date or limitations on use of those devices in the
11 labeling to date.

12 CHAIRPERSON SUZUKI: Other comments,
13 questions? Ms. Howe.

14 MS. HOWE: You had mentioned that there
15 was a defective package. Do you know how it was
16 defective?

17 DR. MULRY: It was a very sketchy report.
18 It really didn't provide a lot of details. It almost
19 sounded like it was a device that somebody may have
20 returned or it had been opened. Somebody was looking
21 at the device and somehow soiled it some. So we're
22 not real sure. It wasn't a very detailed report.

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1 CHAIRPERSON SUZUKI: Okay. Dr. O'Brien.

2 DR. O'BRIEN: Yes. For the over-the-
3 counter prescription devices, how does the patient
4 establish the right fit of the device for his
5 particular mouth?

6 DR. MULRY: Well, we don't have any over-
7 the-counter devices cleared at the present time.

8 DR. O'BRIEN: I thought you mentioned
9 that.

10 DR. MULRY: Well, let me clarify. We
11 consider over-the-counter devices if one were to be
12 cleared to be medical devices, which would require a
13 510(k) and would be prescription devices at the
14 present time, but to date we have not cleared any
15 over-the-counter devices for over-the-counter dental
16 mouthguards.

17 DR. O'BRIEN: Okay.

18 CHAIRPERSON SUZUKI: Thank you for the
19 clarification.

20 DR. MULRY: Thank you.

21 CHAIRPERSON SUZUKI: Any others from the
22 panel?

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1 (No response.)

2 CHAIRPERSON SUZUKI: Okay. At this time
3 we have an open comment session concerning the
4 proposed classification of dental mouthguards. There
5 are two companies that wish to present, and I'd like
6 to first call on Dental Concepts.

7 And you'll have designated about ten
8 minutes to present, please, and please come to the
9 microphone and identify yourself.

10 Thank you, and this presentation and
11 discussion will be related primarily to
12 classification.

13 MR. LESTER: Good morning. My name is
14 Michael Lester. I am president of Dental Concepts.

15 Okay. Thank you.

16 Dental Concepts is a company that was
17 founded by a dentist, Dr. Eugene Wagner, in 1981.
18 It's built around the belief that self-care is a
19 critical element in overall oral health. Basically
20 Dr. Wagner's philosophy was that it was a partnership
21 between the dentist and the patient for oral care, and
22 the result is a line of products that you can see

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1 depicted along the bottom of the screen. Some of them
2 you may recognize from local drugstores and food
3 stores and that kind of thing. It's a line of
4 interdental cleaners, picks, gum massagers, the kind
5 of things that people, consumers, should do at home to
6 foster better oral care.

7 We also market two products for Bruxism.
8 One is called NightGuard, and it has been sold in the
9 same channels that all of our other business is, which
10 is essentially retail stores, since 1997.

11 The second product is called BruxGuard,
12 which we sell to dentists for chair side use, and
13 that's been sold since 2003.

14 Dr. Mulry has already described bruxism.
15 Essentially what we put up here is the dictionary
16 definition, which describes bruxism as a habit. I
17 think the important thing about that is that it is a
18 habit that may, in fact, lead to a medical condition,
19 but in and of itself it really is a commonplace and
20 everyday habit. It occurs, according to the ADA, in
21 up to 90 percent of the population at one time or
22 another. They have a fairly broad definition of

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1 bruxism, which includes clenching and pencil chewing
2 and cheek biting, and so on.

3 Night time teeth grinding, as everyone
4 knows, if it's left untreated can be damaging. It
5 also produces an absolutely awful sound, and it can be
6 very annoying to your sleep partner, to say the least.

7 The management of bruxism is fairly simple
8 and straightforward, and that is to put something
9 between the teeth. You have two hard surfaces rubbing
10 together and doing damage and essentially what you
11 want to do if you're a dentist or a consumer is to put
12 something in between them.

13 Obviously if you cushion the teeth you'll
14 also eliminate noise. We use in both products, we use
15 something that we're referring to here as boil and
16 bite technology. It's essentially a system that I
17 think just about everyone is familiar with. If you've
18 ever used an athletic mouthguard certainly you're
19 familiar with it. You drop a mold into a pot of
20 boiling water and shape the mold to the teeth, and
21 then the mold hardens as it cools.

22 What you're left with is a bite plate that

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1 serves as the necessary cushion. It's held in place
2 by suction. The suction is produced by the shaping of
3 the device up around the teeth and gums.

4 It's very easy for consumers to use, and
5 as I said, it's a familiar fitting system. Something
6 in the order of 20 to 30 million athletic mouthguards
7 are sold every year, and by and large they use this
8 technology.

9 This is what the NightGuard product looks
10 like, and I'd like to point out a couple of the
11 features to you. First of all, it's available in
12 three sizes. You may be able to see in the
13 illustration on the left, the one with the hand in it,
14 that there's a channel built into the device. That
15 channel is to make sure that the teeth are centered so
16 that the anterior-posterior positioning is correct.
17 And the teeth have nowhere else to go basically but
18 into that channel.

19 The thickness of the bit place portion,
20 the portion under the teeth is assured by the fact
21 that in the fitting you don't bite down. All you do
22 is to bite firmly and then shape the device up around

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1 the teeth so that the bite place portion is left with
2 one and a half to two millimeters of thickness, and
3 it's a uniform thickness all the way around.

4 There's also -- I'm not sure if you can
5 see it -- but in the right-hand illustration it may be
6 a little clearer. There's a centering device.
7 There's a guide point in the center so that the
8 lateral fit is a little bit easier to accomplish.

9 This is essentially what a formed product
10 looks like.

11 The BruxGUard, which I mentioned earlier,
12 is identical to the NightGuard, except for the way
13 it's labeled and the way it's marketed. It has a
14 510(k) clearance and has had since 2003. It offers
15 only professional instructions for fitting. It's
16 designed for the dentist to fit at chair side. It
17 includes medical claims, including claims having to do
18 with short term pain relief, prevention of chronic
19 tension, prevention of TMJ syndrome.

20 This device is sold only through health
21 care professionals and is one of the ones that Dr.
22 Mulry mentioned earlier.

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1 Our proposed classification is Class I,
2 510(k) exempt, general controls if marketed solely as
3 a boil and bite physical barrier for nighttime use,
4 and that is a device that makes no medical claims
5 whatsoever, and Class II special controls if marketed
6 for management of medical conditions and sequelae, and
7 of course, making medical claims.

8 Our reasoning is that there should be a
9 distinction within the category based on labeling
10 differences. The FDA commonly imposes different
11 levels of regulation on the same technology based upon
12 its labeled or intended use, and you'll see a more
13 elaborate description of that in our submission.

14 Boil and bite mouthguards intended only as
15 a physical barrier are safe. There have been no
16 reports of injury in the medical literature dealing
17 with soft mouthguards. We're referring to this as a
18 soft mouthguard. An extensive search of the medical
19 literature has shown no reports of the kinds of injury
20 that have been described.

21 It's, I think, important to note that over
22 three million units of our NightGuard product have

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1 been sold since 1997, and that's without a single
2 consumer injury, complaint, or legal action. We
3 haven't had a complaint of injury. We haven't had a
4 call from a dentist. We haven't had a call from a
5 dentist. We haven't had a lawsuit. Essentially we
6 are adverse event free over three million units.

7 The FDA's general controls, GoodNight
8 examples, good manufacturing practice and adverse
9 event reporting are sufficient to provide reasonable
10 assurance of the safety and effectiveness of these
11 products. Therefore, they belong in Class I.

12 Our rationale for Class II is that
13 mouthguards labeled for management of medical
14 conditions and sequelae raised more significant issues
15 and that FDA review of supporting data through the
16 510(k) process may be warranted.

17 In summary, a mouthguard intended only as
18 a boil and bite physical barrier to bruxism should be
19 placed in Class I. A mouthguard intended to manage
20 medical conditions and sequelae should be placed in
21 Class II.

22 Mr. Chairman, before I leave, we also

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1 forgot to add the warnings and caution section to the
2 submission that you have. I have copies here and I'd
3 like to give them to you to be distributed. Okay?

4 CHAIRPERSON SUZUKI: Okay. Please do.

5 While he's doing it, are there any
6 questions from the panel on this presentation? Dr.
7 Demko.

8 DR. DEMKO: My question is the
9 NightGuard. Does it have a hard acrylic base so that
10 where the mandibular teeth touch it that's against
11 hard acrylic, or is it completely soft?

12 MR. LESTER: No, ma'am. It's completely
13 soft, although the density of the plastic on the base
14 portion is harder than the density of the plastic on
15 the upper portion so that the base portion holds its
16 form, but it doesn't hold its form in the way that an
17 acrylic mouthguard does

18 DR. DEMKO: Is there indentation when the
19 mandibular teeth --

20 MR. LESTER: No, ma'am.

21 Yes, sir.

22 DR. ZERO: Is the device -- you said there

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1 were three different sizes. Is one intended to be for
2 children?

3 MR. LESTER: No, no. We specifically say
4 in the labeling that it's not to be used for children.

5 The three sizes are for adults, obviously, women, and
6 men, but the device also -- in the instructions it
7 allows the device to be cut if it's a little too long.

8 You know, it's not the kind of material that can't be
9 trimmed. So if there's any risk of it going too far
10 back, it can be cut, but not for children.

11 CHAIRPERSON SUZUKI: Dr. O'Brien.

12 DR. O'BRIEN: Yes. Are there any studies
13 comparing the accuracy of the fit of these devices
14 compared to the traditional ones, which are made by
15 impression taking?

16 MR. LESTER: No, sir.

17 DR. O'BRIEN: Also, is there any clinical
18 data that exists that shows the noncompliance with the
19 use of the device?

20 One of the problems with mouthguards is
21 that if they don't fit right, they won't report it.
22 They won't complain, but they just won't wear them.

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1 MR. LESTER: Well, nothing formal on that.

2 We do have and have had all the years we've been on
3 the market an unconditional money back guarantee, and
4 the usual retail price for this product is 24.99 in
5 retail stores. So at \$25, I think if somebody wants
6 something that is unsatisfactory, they're probably
7 more likely to send it back to us.

8 What we find is that most often the
9 complaints are not of it didn't fit or it wasn't
10 comfortable. Most often it's "I'm sending you back
11 the medium because I really need the large."

12 But we don't have a historical record of
13 compliance and noncompliance, no.

14 CHAIRPERSON SUZUKI: Thank you.

15 Other questions? Ms. Howe.

16 MS. HOWE: I have a question about that
17 sizing. On the packaging, how do you advise the
18 consumer to select one of the three sizes?

19 MR. LESTER: We use height and body weight
20 as rough guidelines, and we know that it's not as
21 accurate a measurement, but that's the reason that we
22 offer them a money back guarantee if they take the

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1 wrong size.

2 CHAIRPERSON SUZUKI: Dr. Zuniga.

3 DR. ZUNIGA: Just for my clarification,
4 your indications for differences between the
5 NightGuard and the BruxGuard are few or are they the
6 same? Are they slightly different?

7 MR. LESTER: They're the same. They're
8 the same product with different labeling and different
9 instructions for use.

10 DR. ZUNIGA: Then the question is I
11 thought I saw on the BruxGuard you claim prevention of
12 TMJ disorders, and I'm wondering what information or
13 data you have on that.

14 I know the NIH published their consensus
15 report in 1996 indicating that there are no known
16 preventions or prophylactic therapies for TMD.

17 MR. LESTER: That's the 510(k) product.
18 So those claims were, in fact, cleared by the FDA, and
19 all of it, I think, is based on historical and
20 predicate device information. We essentially took
21 labeling for that that was labeling that had already
22 been set by the FDA as approvable labeling for such

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1 devices.

2 CHAIRPERSON SUZUKI: Other questions or
3 comment? Dr. Cochran.

4 DR. COCHRAN: Does your company feel that
5 Bruxism can lead to TMJ problems?

6 MR. LESTER: We will have a presentation
7 on that later on. It will be a lot more authoritative
8 than I can make, but what I've been told about that
9 subject, Doctor, is that it can, but it doesn't
10 necessarily.

11 And we view our over-the-counter product
12 as a product that really is designed for a simple --
13 if I can coin a phrase, simple bruxism that has not
14 become complicated, and you'll see in our labeling
15 that we specifically warn people who have been told
16 that they have TMJ or that have jaw clicking or any of
17 the symptoms that may be associated with TMJ not to do
18 this and to go to the doctor or to go to the dentist.

19 And we also say on our labeling that after
20 no more than three months' use you should take it with
21 you to the dentist and have your dentist confirm that
22 you're doing something good for yourself and not

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1 something bad for yourself.

2 CHAIRPERSON SUZUKI: Other comments,
3 questions? Ms. Howe.

4 MS. HOWE: Will we be hearing this
5 additional information when we consider the over-the-
6 counter issue?

7 MR. LESTER: Yes, yes. That's this
8 afternoon.

9 CHAIRPERSON SUZUKI: Thank you, Mr.
10 Lester.

11 MR. LESTER: Thank you very much.

12 CHAIRPERSON SUZUKI: You may distribute
13 the addendum.

14 Okay. The next presenter is Respironics.
15 Ms. Yurko.

16 Okay. We'll continue to have an open
17 comment session regarding the proposed classification
18 of dental mouthguards. I'd like to ask if there's
19 anyone else in the audience who wishes to address the
20 panel.

21 (No response.)

22 CHAIRPERSON SUZUKI: Okay. If not, I will

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1 ask Ms. Shulman to lead the panel to complete the
2 classification forms.

3 DR. O'BRIEN: Mr. Chairman, what is the
4 FDA proposed classification for these devices?

5 CHAIRPERSON SUZUKI: It's II, but I can
6 have Ms. Shulman review that again.

7 DR. O'BRIEN: All right.

8 CHAIRPERSON SUZUKI: If you want to put up
9 the slide.

10 Okay. As we're filling out the forms, at
11 this time in light of the discussions and
12 presentations, I'd like to ask the panel if you'd like
13 any further discussion on possibly splitting the
14 classification to I and IIs. Mr. Schechter?

15 MR. SCHECHTER: I guess I have a question
16 for the FDA, maybe Dr. Mulry. Has the FDA given any
17 consideration as to whether there should be a split in
18 the classification as suggested by Dental Concepts?

19 MR. LESTER: No, we haven't because we
20 have viewed to date that all dental mouthguards are
21 prescription devices and require a 510(k), and I think
22 we have looked at the issue of bruxism as being more

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1 than just a benign condition, but one that affects the
2 whole oral musculature, the TMJ and can have an impact
3 not only on the teeth, but can cause jaw pain, chronic
4 facial pain, et cetera.

5 So we have viewed it as a global -- as one
6 type of classification, whether no matter what the
7 design has been we have looked at it as all being of
8 assistance in the treatment of orificial pain. So,
9 no, we haven't.

10 MR. SCHECHTER: So then I guess to
11 clarify --

12 CHAIRPERSON SUZUKI: Mr. Schechter again.

13 MR. SCHECHTER: Thank you.

14 When we have a discussion later about
15 possible over-the-counter use, even if the panel
16 recommends that some are available for over-the-
17 counter use, they would still all be Class II devices;
18 is that correct?

19 MR. LESTER: That's for the panel to
20 determine, I would believe.

21 MR. SCHECHTER: Well, I'm just asking if
22 that's the FDA's suggestion.

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1 MR. LESTER: At this point in time we do
2 believe that Class II guidance document, special
3 controls, would be the appropriate classification for
4 these devices.

5 MR. SCHECHTER: Okay.

6 CHAIRPERSON SUZUKI: Other questions? Dr.
7 Demko.

8 DR. DEMKO: Well, I do want to make a
9 comment on the major researchers out there who are now
10 looking at bruxism, which is going to be Gene
11 Levigne's group in Montreal, Tommy Shoholm in
12 Stockholm, Mea Waki in Tokyo, that these people when
13 they look at bruxism, Mea Waki's work says that
14 according to his research, 80 percent of -- when we
15 study bruxism in the laboratory, they're actually
16 looking at rhythmic masseter movement; that 80 percent
17 of what he sees is related to very mild acid reflux.
18 So you're talking about bruxism being a symptom quite
19 often of things that could be more serious diseases,
20 which is one of the reasons to keep this within the
21 realm of the dentist viewpoint because if there's acid
22 reflux into the mouth, you'll see the damage on the

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1 teeth. It is different from bruxism.

2 Other times it can be central nervous
3 system people who have organic brain disease. A lot
4 of them are bruxers. It is not truly a habit. It is
5 something that has a cause, especially nocturnal
6 bruxism, which is when most damage is done.

7 These guards are not made to be worn
8 during the day when it would be a habitual thing.
9 They're made to be worn at night when it is a central
10 nervous system reflex to something going on in the
11 body.

12 CHAIRPERSON SUZUKI: Thank you.

13 Ms. Howe.

14 MS. HOWE: I'd like to ask clarification
15 on that. If the ADA is saying that 90 percent of the
16 population has some kind of a grinding problem or
17 clinching problem, what percent of the population are
18 you addressing with the bruxism diagnosis?

19 DR. DEMKO: When the ADA said that, they
20 included all oral habits, nail biting and biting
21 inside of your cheek. Those are truly habits. If
22 you're looking at this guard is made to be worn at

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1 night with nocturnal bruxism, which is a different
2 animal from a daytime habit, so if you read the
3 article in the ADA, you'll actually see that those
4 people who are nocturnal bruxers are a much smaller
5 number and probably run closer to about eight to ten
6 percent of the population, but they're the ones who
7 are doing damage to their teeth, not daytime bruxers.

8 Clinchers daytime, those people will end
9 up with muscle pain if they're daytime clenchers, but
10 again, these guards are not made to be worn during the
11 day.

12 CHAIRPERSON SUZUKI: Other comments,
13 questions?

14 The Chair would still like to maintain a
15 motion one way or the other as to whether or not to
16 split this classification or to proceed forward as
17 Class II. Can I have a motion from any panel member?

18 DR. DEMKO: I make a motion that it should
19 be a Class II.

20 CHAIRPERSON SUZUKI: Okay. Is there a
21 second?

22 DR. O'BRIEN: Yes, I second it.

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1 CHAIRPERSON SUZUKI: Okay. It as been
2 moved and seconded. All in favor on the panel -- any
3 questions or discussion?

4 MS. HOWE: Question.

5 CHAIRPERSON SUZUKI: Ms. Howe.

6 MS. HOWE: My understanding, this does not
7 preclude us from our follow-up discussion on over-the-
8 counter and to consider others as Class I. True?

9 CHAIRPERSON SUZUKI: That's correct.

10 MS. HOWE: Thank you.

11 CHAIRPERSON SUZUKI: That's the next
12 topic, I believe.

13 Dr. Runner?

14 DR. RUNNER: I think just to clarify this,
15 this is Susan Runner.

16 The classification doesn't have anything
17 to do with OTC or not. You can have an OTC product
18 that's Class II as well.

19 MS. HOWE: Okay.

20 CHAIRPERSON SUZUKI: Okay. Thank you.

21 Any other questions?

22 (No response.)

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1 CHAIRPERSON SUZUKI: Can you repeat the
2 motion, Dr. Demko?

3 DR. DEMKO: I make a motion that we label
4 all dental mouthguards as Class II devices.

5 CHAIRPERSON SUZUKI: Okay. I will poll
6 the members. All in favor or opposed? Dr. Cochran.

7 DR. COCHRAN: In favor.

8 CHAIRPERSON SUZUKI: Dr. O'Brien?

9 DR. O'BRIEN: In favor.

10 CHAIRPERSON SUZUKI: Dr. Zero.

11 DR. ZERO: In favor.

12 CHAIRPERSON SUZUKI: Dr. Zuniga.

13 DR. ZUNIGA: In favor.

14 CHAIRPERSON SUZUKI: Ms. Howe.

15 MS. HOWE: Opposed.

16 CHAIRPERSON SUZUKI: Mr. Schechter.

17 MR. SCHECHTER: Opposed.

18 CHAIRPERSON SUZUKI: Dr. Bakland.

19 DR. BAKLAND: In favor.

20 CHAIRPERSON SUZUKI: Dr. Demko.

21 DR. DEMKO: In favor.

22 CHAIRPERSON SUZUKI: It passes. So we

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1 will proceed with a position of Class II.

2 MS. SHULMAN: This is Marjorie Shulman.

3 Just for clarification, that was just to
4 decide if we were going to go through the forms twice
5 to split the record or not. It's not officially
6 classified until we go through the form.

7 CHAIRPERSON SUZUKI: Right. We're
8 proceeding with the discussion that it will be Class
9 II.

10 MS. SHULMAN: Okay. Again on the general
11 classification questionnaire, your name, the date, the
12 generic type of device, and then the first question.

13 CHAIRPERSON SUZUKI: Okay.

14 MS. SHULMAN: Is the device life
15 sustaining or life supporting? .

16 CHAIRPERSON SUZUKI: Okay. Beginning with
17 Dr. Cochran.

18 DR. COCHRAN: No.

19 CHAIRPERSON SUZUKI: Dr. O'Brien.

20 DR. O'BRIEN: No.

21 CHAIRPERSON SUZUKI: Dr. Zero?

22 DR. ZERO: No.

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1 CHAIRPERSON SUZUKI: Dr. Zuniga.

2 DR. ZUNIGA: No.

3 CHAIRPERSON SUZUKI: Representatives, Ms.

4 Howe.

5 MS. HOWE: No.

6 CHAIRPERSON SUZUKI: Mr. Schechter.

7 MR. SCHECHTER: No.

8 CHAIRPERSON SUZUKI: Dr. Bakland.

9 DR. BAKLAND: No.

10 CHAIRPERSON SUZUKI: And Dr. Demko.

11 DR. DEMKO: No.

12 CHAIRPERSON SUZUKI: Okay. Unanimously

13 no.

14 MS. SHULMAN: Thank you.

15 Question 2, is the device for use which is
16 of substantial importance in preventing impairment of
17 human health?

18 CHAIRPERSON SUZUKI: Okay. Beginning
19 against with the panel, Dr. Cochran.

20 DR. COCHRAN: No.

21 CHAIRPERSON SUZUKI: Dr. O'Brien.

22 DR. O'BRIEN: Yes.

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1 CHAIRPERSON SUZUKI: Dr. Zero.
2 DR. ZERO: No.
3 CHAIRPERSON SUZUKI: Dr. Zuniga.
4 DR. ZUNIGA: No.
5 CHAIRPERSON SUZUKI: Ms. Howe.
6 MS. HOWE: No.
7 CHAIRPERSON SUZUKI: Mr. Schechter.
8 MR. SCHECHTER: No.
9 CHAIRPERSON SUZUKI: Dr. Bakland.
10 DR. BAKLAND: No.
11 CHAIRPERSON SUZUKI: Dr. Demko.
12 DR. DEMKO: No.
13 CHAIRPERSON SUZUKI: Okay. No is the
14 majority.
15 MS. SHULMAN: Thank you.
16 Number 3: does the device present a
17 potential unreasonable risk of illness or injury?
18 CHAIRPERSON SUZUKI: Okay. Dr. Cochran?
19 DR. COCHRAN: No.
20 CHAIRPERSON SUZUKI: Dr. O'Brien.
21 DR. O'BRIEN: No.
22 CHAIRPERSON SUZUKI: Dr. Zero.

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1 DR. ZERO: No.

2 CHAIRPERSON SUZUKI: Dr. Zuniga.

3 DR. ZUNIGA: No.

4 CHAIRPERSON SUZUKI: The representatives,
5 Ms. Howe.

6 MS. HOWE: No.

7 CHAIRPERSON SUZUKI: Mr. Schechter.

8 MR. SCHECHTER: No.

9 CHAIRPERSON SUZUKI: Dr. Bakland.

10 DR. BAKLAND: No.

11 CHAIRPERSON SUZUKI: Dr. Demko.

12 DR. DEMKO: No.

13 CHAIRPERSON SUZUKI: Okay. Unanimously
14 no.

15 MS. SHULMAN: Thank you.

16 Number four, did you answer yes to any of
17 the above three questions? The answer is no. So we
18 go to number five. Is there sufficient information to
19 determine that general controls are sufficient to
20 provide reasonable assurance of safety and
21 effectiveness?

22 CHAIRPERSON SUZUKI: Okay. Dr. Cochran?

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1 DR. COCHRAN: No.

2 CHAIRPERSON SUZUKI: Dr. O'Brien.

3 DR. O'BRIEN: No.

4 CHAIRPERSON SUZUKI: Dr. Zero.

5 DR. ZERO: No.

6 CHAIRPERSON SUZUKI: Dr. Zuniga.

7 DR. ZUNIGA: No.

8 CHAIRPERSON SUZUKI: Ms. Howe.

9 MS. HOWE: Yes

10 CHAIRPERSON SUZUKI: Mr. Schechter.

11 MR. SCHECHTER: Yes.

12 CHAIRPERSON SUZUKI: Dr. Bakland.

13 DR. BAKLAND: No.

14 CHAIRPERSON SUZUKI: Dr. Demko.

15 DR. DEMKO: No.

16 CHAIRPERSON SUZUKI: Okay. No is the
17 majority.

18 MS. SHULMAN: Thank you.

19 Number six: is there sufficient
20 information to establish special controls in addition
21 to general controls to provide reasonable assurance of
22 safety and effectiveness?

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1 CHAIRPERSON SUZUKI: Dr. Cochran?

2 DR. COCHRAN: Yes.

3 CHAIRPERSON SUZUKI: Dr. O'Brien.

4 DR. O'BRIEN: Yes.

5 CHAIRPERSON SUZUKI: Dr. Zero.

6 DR. ZERO: Yes.

7 CHAIRPERSON SUZUKI: Dr. Zuniga.

8 DR. ZUNIGA: Yes.

9 CHAIRPERSON SUZUKI: Ms. Howe.

10 MS. HOWE: Yes.

11 CHAIRPERSON SUZUKI: Mr. Schechter.

12 MR. SCHECHTER: Yes.

13 CHAIRPERSON SUZUKI: Dr. Bakland.

14 DR. BAKLAND: Yes.

15 CHAIRPERSON SUZUKI: Dr. Demko.

16 DR. DEMKO: Yes.

17 CHAIRPERSON SUZUKI: Okay. Unanimously

18 yes.

19 MS. SHULMAN: Thank you.

20 If yes, classify in II and go to Item 7.

21 If there is sufficient information to establish
22 special controls to provide reasonable assurance of

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1 safety and effectiveness, identify the special
2 controls needed to provide such reasonable assurance
3 for Class II.

4 CHAIRPERSON SUZUKI: Beginning with Dr.
5 Cochran.

6 DR. COCHRAN: The guidance document.

7 CHAIRPERSON SUZUKI: Dr. O'Brien?

8 DR. O'BRIEN: The guidance document.

9 CHAIRPERSON SUZUKI: Dr. Zero.

10 DR. ZERO: Guidance document.

11 CHAIRPERSON SUZUKI: Dr. Zuniga.

12 DR. ZUNIGA: Guidance document.

13 CHAIRPERSON SUZUKI: Ms. Howe.

14 MS. HOWE: Guidance document.

15 CHAIRPERSON SUZUKI: Mr. Schechter.

16 MR. SCHECHTER: Guidance document.

17 CHAIRPERSON SUZUKI: Dr. Bakland.

18 DR. BAKLAND: Guidance documents.

19 CHAIRPERSON SUZUKI: Dr. Demko.

20 DR. DEMKO: Guidance document.

21 CHAIRPERSON SUZUKI: Unanimously guidance
22 document.

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1 MS. SHULMAN: Thank you.

2 Question 8 and 9 only have to do with
3 performance standards. We may skip. Question 10 only
4 has to do with Class III devices. We can move on to
5 Question 11. Identify the need of restrictions. The
6 pre-amendment I was a prescription device. So the
7 first one would apply.

8 Is there anything else that should be
9 added or any comments?

10 CHAIRPERSON SUZUKI: Okay. Questions,
11 comments on number 11?

12 (No response.)

13 CHAIRPERSON SUZUKI: Okay. Mr. Schechter.

14 MR. SCHECHTER: I don't know if this is
15 the appropriate time since we're going to talk later
16 on about whether these could possibly be available
17 over the counter, but we're also talking about it now.

18 So in other classifications we have said that they
19 can be available prescription and OTC. Do we need to
20 discuss that now or can we pass the question on until
21 the afternoon?

22 MS. SHULMAN: This is Marjorie Shulman.

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1 The other ones that we discussed were
2 available prescription and over-the-counter pre-
3 amendment, and at that time, pre-1976.

4 MR. SCHECHTER: Okay.

5 MS. SHULMAN: As far as we know, this one
6 was prescription pre-amendment. So since we're
7 classifying the pre-amendment device, the prescription
8 should stay.

9 CHAIRPERSON SUZUKI: Okay. Does that
10 answer your question?

11 MR. SCHECHTER: I'm not sure. Should we
12 be voting now to have both possibly, indications,
13 prescription and OTC, or not?

14 MS. SHULMAN: No, not at this time. I
15 think that's a discussion for later.

16 MR. SCHECHTER: Okay. Thank you.

17 CHAIRPERSON SUZUKI: Any other questions
18 or comments before I poll the panel?

19 (No response.)

20 CHAIRPERSON SUZUKI: Okay. Dr. Cochran.

21 DR. COCHRAN: First box.

22 CHAIRPERSON SUZUKI: Dr. O'Brien.

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1 DR. O'BRIEN: First box.

2 CHAIRPERSON SUZUKI: Dr. Zero.

3 DR. ZERO: First box.

4 CHAIRPERSON SUZUKI: Dr. Zuniga.

5 DR. ZUNIGA: First box.

6 CHAIRPERSON SUZUKI: Ms. Howe.

7 MS. HOWE: First box.

8 CHAIRPERSON SUZUKI: Mr. Schechter.

9 MR. SCHECHTER: First box.

10 CHAIRPERSON SUZUKI: Dr. Bakland.

11 DR. BAKLAND: First box.

12 CHAIRPERSON SUZUKI: Dr. Demko.

13 DR. DEMKO: First box.

14 CHAIRPERSON SUZUKI: Unanimously first
15 box.

16 MS. SHULMAN: Thank you.

17 Okay. We can move on to the second sheet,
18 the supplemental data sheet. Again, your name on the
19 top of the form, the generic type of device, the
20 advisory panel, and is the device an implant? The
21 answer is no.

22 Question 4, is the indications for use

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1 that was presented during the panel meeting. You can
2 fill in the form "as presented" or you can add
3 anything or comment at this time.

4 CHAIRPERSON SUZUKI: Any comments on
5 number four from the panel?

6 (No response.)

7 CHAIRPERSON SUZUKI: Okay. None.

8 MS. SHULMAN: Thank you.

9 We can move on to number five, the
10 identification of the risks to health presented by the
11 device. Again, were presented in the panel
12 presentation. If there's any comments or you can say
13 "as presented."

14 CHAIRPERSON SUZUKI: Any questions on
15 number five from the panel?

16 (No response.)

17 CHAIRPERSON SUZUKI: None.

18 MS. SHULMAN: Thank you.

19 Number six, the recommended advisory
20 classification. Priority classification is II and the
21 priority, again, high, medium or low.

22 CHAIRPERSON SUZUKI: Okay. High, medium

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1 or low. Dr. Cochran.

2 DR. COCHRAN: Medium.

3 CHAIRPERSON SUZUKI: Dr. O'Brien.

4 DR. O'BRIEN: Medium.

5 CHAIRPERSON SUZUKI: Dr. Zero.

6 DR. ZERO: Medium.

7 CHAIRPERSON SUZUKI: Dr. Zuniga.

8 DR. ZUNIGA: Medium.

9 CHAIRPERSON SUZUKI: Ms. Howe.

10 MS. HOWE: Medium.

11 CHAIRPERSON SUZUKI: Mr. Schechter.

12 MR. SCHECHTER: Medium.

13 CHAIRPERSON SUZUKI: Dr. Bakland.

14 DR. BAKLAND: Low.

15 CHAIRPERSON SUZUKI: Dr. Demko.

16 DR. DEMKO: Medium.

17 CHAIRPERSON SUZUKI: Okay. The majority

18 is medium priority.

19 MS. SHULMAN: Thank you.

20 Number seven we may skip because the
21 device is not an implant or life sustaining or life
22 supporting.

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1 And number eight, the summary of
2 information, information including clinical experience
3 or judgment upon which the classification
4 recommendation is based, again, you may say as
5 presented in the panel meeting or you may add anything
6 else at this time.

7 (No response.)

8 MS. SHULMAN: If there are no comments, we
9 can go to Question 9. The identification of any
10 needed restrictions on the use of the device, special
11 labeling banning prescription use. We have
12 prescription use. Any others?

13 CHAIRPERSON SUZUKI: Dr. Demko.

14 DR. DEMKO: I would simply add that
15 nocturnal bruxism may be an indication of a more
16 serious medical condition, such as acid reflux
17 disease.

18 MS. SHULMAN: Thank you. Noted.

19 CHAIRPERSON SUZUKI: Okay. Other
20 comments? Mr. Schechter.

21 MR. SCHECHTER: In the guidance document
22 that FDA will produce perhaps give consideration to

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1 two levels of requirements in terms of labeling and
2 information submitted based on what dental concepts
3 presented here today. I can say that I went out and
4 bought the NightGuard just to give it a try, and it's
5 very simple to use. I would hate for this
6 classification to, you know, block that product.

7 So just give it consideration in the
8 guidance.

9 MS. SHULMAN: Thank you.

10 CHAIRPERSON SUZUKI: Thank you. Any other
11 comments on number nine?

12 (No response.)

13 CHAIRPERSON SUZUKI: Okay. None

14 MS. SHULMAN: Thank you.

15 Number ten we may skip because that is for
16 Class 1 devices.

17 Number 11, if it's recommended for Class
18 I, we would like your opinion on whether we should
19 exempt it from premarket notification.

20 CHAIRPERSON SUZUKI: Okay. Either exempt
21 or nonexempt. Dr. Cochran.

22 DR. COCHRAN: Not exempt.

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1 CHAIRPERSON SUZUKI: Dr. O'Brien.

2 DR. O'BRIEN: Not exempt.

3 CHAIRPERSON SUZUKI: Dr. Zero.

4 DR. ZERO: Not exempt.

5 CHAIRPERSON SUZUKI: Dr. Zuniga.

6 DR. ZUNIGA: Nonexempt.

7 CHAIRPERSON SUZUKI: Ms. Howe.

8 MS. HOWE: Exempt.

9 CHAIRPERSON SUZUKI: Mr. Schechter.

10 MR. SCHECHTER: Not exempt.

11 CHAIRPERSON SUZUKI: Dr. Bakland.

12 DR. BAKLAND: Not exempt.

13 CHAIRPERSON SUZUKI: Dr. Demko.

14 DR. DEMKO: Not exempt.

15 CHAIRPERSON SUZUKI: Okay. The majority
16 is not exempt.

17 MS. SHULMAN: Thank you.

18 Number 12, any other existing standards
19 known?

20 CHAIRPERSON SUZUKI: Okay. Comments or
21 questions from the panel on number 12?

22 DR. O'BRIEN: Yes.

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1 CHAIRPERSON SUZUKI: Dr. O'Brien speaking.

2 DR. O'BRIEN: Have you checked with the
3 American Dental Association? I'd be surprised if they
4 didn't have some type of standard for mouthguards
5 since they're so widely used.

6 MS. SHULMAN: I will ask the division.

7 DR. O'BRIEN: Not aware of any? Okay.

8 MS. SHULMAN: They're not aware of any.

9 Okay. If you'll please vote on the form
10 as filled out as a Class II device requiring premarket
11 notification subject to the special controls guidance
12 document.

13 CHAIRPERSON SUZUKI: Okay. We'll next
14 vote on the supplemental data sheet as filled out. I
15 ask either in favor or opposed beginning with Dr.
16 Cochran.

17 DR. COCHRAN: In favor.

18 CHAIRPERSON SUZUKI: Dr. O'Brien.

19 DR. O'BRIEN: In favor.

20 CHAIRPERSON SUZUKI: Dr. Zero.

21 DR. ZERO: In favor.

22 CHAIRPERSON SUZUKI: Dr. Zuniga.

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1 DR. ZUNIGA: In favor.

2 CHAIRPERSON SUZUKI: Representatives, Ms.
3 Howe.

4 MS. HOWE: In favor.

5 CHAIRPERSON SUZUKI: Mr. Schechter.

6 MR. SCHECHTER: In favor.

7 CHAIRPERSON SUZUKI: Dr. Bakland.

8 DR. BAKLAND: In favor.

9 CHAIRPERSON SUZUKI: Dr. Demko.

10 DR. DEMKO: In favor.

11 CHAIRPERSON SUZUKI: Okay. It passed in
12 favor.

13 MS. SHULMAN: Thank you.

14 CHAIRPERSON SUZUKI: Okay. We'll take a
15 15 minute recess at this time.

16 (Whereupon, the foregoing matter went off
17 the record at 9:23 a.m. and went back on
18 the record at 9:49 a.m.)

19 CHAIRPERSON SUZUKI: We will now call the
20 meeting back to order.

21 We will now hold the second open public
22 hearing session for this meeting. If there are any

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1 individuals wishing to address the panel, please raise
2 your hands and identify yourselves at this time.

3 Okay. Mr. Lester. And you're reminded
4 that the same identification processes, disclosure
5 requirements, and ten minute time limit announcement
6 at the first open public hearing session yesterday
7 will apply to this session as well.

8 MR. LESTER: Thank you.

9 This is an unscheduled appearance, and
10 it's basically in response to a statement that was
11 made earlier that I'd like to issue a clarification
12 of. I had said that bruxism devices, such as the
13 NightGuard, had been on the market. I think I said
14 had been on the market for some years previous to our
15 appearance in 1997, and this bears on the statement
16 that was made that there were no OTC pre-amendment
17 devices.

18 So the next two speakers, me and the next
19 speaker, are both going to bring you some specific
20 evidence of pre-amendment devices, pre-1976 devices
21 that were sold over the counter.

22 I'm going to hand out, if I may, Mr.

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1 Chairman, this ad that appeared in the New York Times.

2 Unfortunately, it's a copy of a fax and is only
3 barely legible. So if I may, I'd like to just read
4 the copy from this so that when you have a look at it
5 you'll be able to understand what the words are. Is
6 that okay?

7 CHAIRPERSON SUZUKI: Okay. Certainly.

8 MR. LESTER: The ad is dated July 15th,
9 1973. It appeared in the New York Times. I will give
10 you a bad copy of it, but we'll have much more clear
11 copies of it to issue at some later date.

12 Basically the ad reads as follows:
13 "Instant relief for people who grind their teeth at
14 night. Grinding causes bruxism." In parens it says,
15 "Excessive wear of teeth which may cause severe facial
16 pain affecting the jaws, ears, teeth, gums, and
17 causing headaches, stiffness to neck muscles and
18 changing the shape of the face itself."

19 "Mouthpiece, which is what it's called, is
20 a tasteless, odorless, plastic device that conforms to
21 your teeth and prevents the teeth from contact."

22 So that's my own handwriting which is

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1 worse than the ad, and essentially that's my
2 statement, and I'd like to give this ad to you if I
3 may.

4 CHAIRPERSON SUZUKI: Certainly.

5 Okay. Other speakers? Please come to the
6 podium and identify yourself please.

7 MR. JOLLY: Good morning. My name is
8 Charles Jolly. I am Secretary and General Counsel of
9 Prestige Brands Holdings, a New York Stock Exchange
10 publicly traded company.

11 I apologize for my informality. I was not
12 planning to speak this morning, but I wish to provide
13 the panel and the FDA with some information that I
14 think has relevance to your deliberations given the
15 presentation which I've observed this morning and the
16 things that I've heard.

17 Prestige Brands is currently evaluating
18 two acquisition prospects in the nighttime dental
19 guard category, one of which actually was the subject
20 of a patent issued in 1975 to a Dr. Gilbert Mann.
21 This device we have found was not only offered for
22 sale commercially pre-amendment, but it was actually

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1 advertised in Reader's Digest magazine and has
2 continued to be commercialized from before the medical
3 device amendments were passed in the 1974-75 period,
4 but continuously up until the present.

5 As I say, Prestige Brands is looking at
6 two current prospects for acquisition. We have a copy
7 of Dr. Mann's patent, and I think the copies have just
8 arrived, which I would be pleased to submit to the
9 panel, which will demonstrate that these devices not
10 only have been in the marketplace; they were all over-
11 the-counter devices, and as I say, preceded the
12 passage of the medical device amendments.

13 My understanding is that the FDA staff
14 believed that these devices have been prescription
15 devices since their development in the 1940s. My
16 research and my investigation would indicate
17 otherwise.

18 As I say, I came to this meeting simply to
19 observe what was going on, but hearing the testimony I
20 feel compelled to provide for the record the findings,
21 and I have a copy of Dr. Mann's patent, which I will
22 submit, but I would also be prepared to make a more

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1 detailed submission to the panel and to the agency to
2 document the existence of this position.

3 Given those circumstances, I would
4 respectfully suggest that since the FDA staff had
5 predicated the classification decision on the fact
6 that all of these devices have always been
7 prescription devices, the panel may wish to reconsider
8 that vote.

9 Secondly, I would like to point out as we
10 start to consider the OTC segment, I'm certainly not a
11 physician and don't pretend to address the medical
12 questions with any classification. What I do know is
13 that these devices save literally millions of teeth
14 from chipping and grinding and surface wear., and so I
15 think the panel needs to take into consideration the
16 benefit-risk calculation, that is, millions of teeth
17 being saved from damage and harm and patients whose
18 sleep partners are sleepless and all of the other
19 issues which go along with having these devices mae
20 over the counter.

21 Jeff, do we have copies?

22 Okay. With the Chairman's permission,

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1 we'll try to -- I have a copy of the original Gilbert
2 Mann patent, dated December 9th of 1975, which I would
3 be pleased to submit for the record, and I would be
4 pleased to answer any questions.

5 I can assure you that Prestige Brands,
6 when we do our due diligence in looking at
7 acquisitions, we look very carefully into the history
8 and the background of our prospective candidates, and
9 one of the things I am pleased to tell you that is in
10 the millions of these units that have been sold OTC in
11 the two companies that we're now examining, we have
12 yet to find a single instance of adverse reaction,
13 harm, injury, legal complaint or any other adverse
14 consequence of using these devices, and I think that
15 speaks well to their utility in the hands of the
16 consumer.

17 CHAIRPERSON SUZUKI: Does the panel have
18 any questions or discussion to this presenter? Dr.
19 Zuniga.

20 DR. ZUNIGA: Your device you're describing
21 was for an athletic mouthguard and bruxism or bruxism
22 alone?

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1 MR. JOLLY: The devices that we're looking
2 at are for nighttime tooth grinding, and if we
3 consider that bruxism, fine, but it is for that
4 expression of the symptom.

5 CHAIRPERSON SUZUKI: Any other questions
6 or discussion? Dr. Demko.

7 DR. DEMKO: My question is that the patent
8 was granted in 1975. What proof do you have it was
9 over the counter in 1976?

10 MR. JOLLY: We've actually been in contact
11 with Dr. Mann and his associates, and the
12 commercialism of the product actually preceded the
13 patent. As you know, you can file for a patent
14 before, and I would be prepared to submit for the
15 record documentation that the product, in fact, was
16 commercialized even prior to the issuance of the
17 patent.

18 CHAIRPERSON SUZUKI: Other questions? Ms.
19 Howe.

20 MS. HOWE: Do you know if the American
21 Dental Association has been asked to look at the
22 product and add their endorsement?

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1 MR. JOLLY: I'm sorry. I didn't hear the
2 first part of the question.

3 MS. HOWE: Has the American Dental
4 Association been asked to review the product and
5 endorse it?

6 MR. JOLLY: At this point Prestige is not
7 the owner or sponsor of a product. We were evaluating
8 some products for acquisition, and so I have not had
9 personally any contact with the American Dental
10 Association that I can refer to as a matter of
11 personal knowledge. Perhaps some of the other
12 witnesses will be able to address that question.

13 CHAIRPERSON SUZUKI: Any other questions?
14 Mr. Schechter.

15 MR. SCHECHTER: This question is more for
16 the FDA. If this information is accurate, do you need
17 the panel to revote on the issue of the pre-amendments
18 device or can you just take this information into
19 consideration.

20 MS. SHULMAN: This is Marjorie Shulman.

21 For a matter of clarification, the panel
22 would not make the decision if the device is pre-

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1 amendment or not pre-amendment. We have procedures
2 there in the Office of Device Evaluation, the Center
3 for Devices and Radiological Health to make that
4 determination through our Office of Compliance.

5 However, you may make a motion. You may
6 wish to move to reopen the sheets and discuss that,
7 but it is not up to the panel to make the
8 determination if it is over-the-counter or not.

9 CHAIRPERSON SUZUKI: Or, Ms. Shulman, as
10 an alternative, could this panel make a motion to
11 reconsider the classification based upon evidence
12 provided if it's accurate and then submit to FDA for
13 reclassification?

14 MS. SHULMAN: Yes, that could be done.
15 I'm thinking that there's a number of ways that could
16 be done if pre-amendment status for the over-the-
17 counter is shown. It can be done. Comments can be
18 placed in the proposed reg. There's --

19 DR. COCHRAN: Mr. Chairman.

20 CHAIRPERSON SUZUKI: Yes, Dr. Cochran.

21 DR. COCHRAN: It seems like there are two
22 issues here. One is whether we would actually

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1 reclassify if, indeed, it was over-the-counter prior
2 to 1976. That's one issue.

3 The second issue is if we would not
4 reclassify and leave it as a Class II device, then the
5 only real change that would occur would be in our box
6 number 11 on that second sheet, where we would add the
7 other category in OTC.

8 So I would make a motion that we recommend
9 that the FDA investigate whether it was over-the-
10 counter or not prior to 1976, and if so, we would
11 recommend that we would add an additional box,
12 "other," with OTC as our checkpoint if, indeed, that's
13 the way it comes out.

14 CHAIRPERSON SUZUKI: Is there a second to
15 the motion before we can discuss it?

16 DR. O'BRIEN: Yeah, I'll second the
17 motion.

18 CHAIRPERSON SUZUKI: Okay. Discussion on
19 the motion.

20 Can you repeat the motion one more time,
21 please, Dr. Cochran?

22 DR. COCHRAN: The motion is that the FDA

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1 do through the process to determine if the device was
2 OTC or not. If it was OTC, that the panel would
3 recommend that on Box No. 11 we would recommend that
4 we check that box off and add OTC to that form.

5 CHAIRPERSON SUZUKI: Okay. I'll call the
6 question and I'll poll the panel. Dr. Cochran.

7 DR. COCHRAN: I approve that.

8 CHAIRPERSON SUZUKI: Dr. O'Brien.

9 DR. O'BRIEN: I approve.

10 CHAIRPERSON SUZUKI: Dr. Zero.

11 DR. ZERO: I approve.

12 CHAIRPERSON SUZUKI: Dr. Zuniga.

13 DR. ZUNIGA: I approve.

14 CHAIRPERSON SUZUKI: Ms. Howe.

15 MS. HOWE: I approve and thank the panel
16 for that clarification.

17 CHAIRPERSON SUZUKI: Mr. Schechter.

18 MR. SCHECHTER: I approve.

19 CHAIRPERSON SUZUKI: Dr. Bakland.

20 DR. BAKLAND: Approve.

21 CHAIRPERSON SUZUKI: Dr. Demko.

22 DR. DEMKO: I approve on the basis that

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1 what we're doing is asking the FDA to look into
2 something.

3 CHAIRPERSON SUZUKI: So it passes
4 unanimously. So we will direct the FDA to investigate
5 that and follow through.

6 MR. JOLLY: Thank you.

7 CHAIRPERSON SUZUKI: Dr. Lin.

8 DR. LIN: I started my report now up to
9 now that all that mouthguard device we have created,
10 all clear as a prescription device, but now that the
11 question posed to the panel that based on the
12 information provided by the industry that this
13 mouthguard can be marketed as OTC or not, that's the
14 issue I think that we put to the panel.

15 This is not the way that FDA should
16 investigate whether this product is marketed as OTC
17 prior to 1976. That's a totally different issue.

18 CHAIRPERSON SUZUKI: Okay. Thank you.

19 Okay. We have seven more minutes for the
20 open public session. Are there anymore individuals
21 who would like to come forward? Please come forward
22 and identify yourself, please.

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1 MR. DIACOPOULOS: My name is Elias
2 Diacopoulos.

3 CHAIRPERSON SUZUKI: Wait. Can you speak
4 into the microphone please?

5 MR. DIACOPOULOS: My name is Elias
6 Diacopoulos. I'm with Respironics. I'm a Director of
7 Research and Development for a Sleep Well Ventures
8 business unit which is part of Respironics.

9 I do have a prepared statement to recite.
10 There were copies outside, but I did notice that it
11 was the incorrect revision. I did bring 30 copies
12 just in case. May I hand those out, please?

13 CHAIRPERSON SUZUKI: Certainly.

14 MR. DIACOPOULOS: I will leave some of the
15 extras out from for the rest of the public.

16 Thank you for the opportunity to
17 participate today. Respironics is a worldwide leader
18 in providing solutions to the sleep and respiratory
19 markets. Our products and programs help clinicians
20 and patients manage sleep problems. Our focus at this
21 meeting is to address three potential concerns
22 regarding over-the-counter, OTC, use of occlusal split

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1 bruxism therapy.

2 Number one, preliminary research validates
3 that occlusal splints for the treatment of bruxism can
4 aggravate obstructive sleep apnea, OSA.

5 Number two, preliminary evidence also
6 indicates that bruxism may be a reflexive response to
7 a reduced airway, that is, airway occlusion due to OSA
8 or enlarged tonsils.

9 And, number three, occlusal splints have
10 documented side effects associated with the oral
11 dryness, pain, et cetera.

12 Our purpose in attending this meeting is
13 to educate the audience given that FDA has previously
14 determined, based on the outcomes of the joint meeting
15 of the FDA dental products and ear, nose and throat
16 panels in October 2004, that it will not allow the OTC
17 marketing of intraoral devices for snoring or OSA.

18 This decision was made based on the risks
19 involved with the selection, fit, and use of these
20 devices, notwithstanding the potential to incorrectly
21 treat a more critical diagnosis, such as OSA.

22 Clinical use of mandibular advancement devices,

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1 MADs. In clinical dentistry and sleep medicine, the
2 use of mandibular advancement devices is a recognized
3 management strategy for two respiratory disturbances
4 during sleep: snoring and sleep apnea. In sleep
5 medicine, snoring and sleep apnea are classified under
6 obstructive sleep apnea and hypopnea syndrome, OHAHS.

7 Although snoring is found in 25 percent of the adult
8 population, the prevalence of OHAHS when estimated
9 with sleep PSG recordings is around two to four
10 percent.

11 Clinicians should be aware that patients
12 who complain about snoring may suffer from undiagnosed
13 sleep apnea, a medical condition that carries an
14 increased risk of cardiovascular disease, including
15 hypertension, stroke, daytime sleepiness, altered
16 memory, enuresis, performance deficit, lost
17 productivity, reduced quality of life, and periodic
18 leg movement during sleep.

19 At the other end of the sleep disordered
20 breathing spectrum lies snoring which affects up to 40
21 million Americans. In addition to the physiological
22 co-morbidities, snoring presents patients with

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1 significant social and quality of life impacts.

2 Sleep disorder breathing describes a group
3 of disorders characterized by abnormalities of the
4 respiratory pattern, example, pauses in breathing, or
5 the quality of ventilation during sleep. SDB may
6 affect up to 50 million Americans.

7 OTC oral appliances for treatment of
8 bruxism. In the general population, the estimated
9 prevalence of tooth grinding sleep bruxism is eight
10 percent. The prevalence of pain caused by temporal
11 mandibular disorders, TMD, is eight to 15 percent for
12 women and three percent to ten percent for men. It
13 has been estimated that more than three million oral
14 splints, also called occlusal splints, are fabricated
15 each year in the United States to manage sleep bruxism
16 and TMD. Although the mechanism of action of the
17 split is unknown, it is possible that splints may
18 modify the space between the dental arches. The
19 mandible is then slightly lowered and could be
20 reduced, and the space of the tongue may also be
21 reduced.

22 This leads one to ponder whether using

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1 such a device might alter airway patency especially
2 during sleep. This conjecture is based on the
3 observation that in the sleep of normal subjects the
4 tongue and hyoid bone tend to move backward and airway
5 patency is reduced in the supine position.

6 Moreover, in apnea patients the rationale
7 behind using an MAD is that functional airway patency
8 may be recovered by causing the mandible to protrude.

9 Taking this information into account, as well as the
10 possibility that sleep apnea OHAHS may be under
11 diagnosed in patients treated with oral squint for
12 bruxism or pain caused by TMD, one could hypothesize
13 that the use of single maxillary oral splint may
14 aggravate respiratory disturbance in sleep apneic
15 patients.

16 In support of this hypothesis, research
17 was performed to determine if a group of ten patients
18 with a history of snoring and a recording night
19 confirming the diagnosis of sleep apnea were studied.

20 Data collected during the study included total sleep
21 time, sleep efficiency, and the number of awakenings.

22 Microarousals, apnea/hypopnea index per hour of

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1 sleep, respiratory disturbances indexed per hour of
2 sleep, and percentage of sleeping time with snoring.

3 Results from this study determined that
4 there were no statistical difference in AHI between
5 baseline and occlusal splint nights. However, four
6 patients experienced an aggravation and apnea
7 diagnosis category in the night they used the splint.

8 The HI was increased by more than 50 percent in five
9 of the ten patients.

10 These RDI showed a 30 percent increase
11 from baseline to splint nights. The percentage of
12 sleeping time with snoring also increased by 40
13 percent with the splint.

14 Based on these results, one may conclude
15 that the use of an occlusal splint is associated with
16 a risk of aggravation of respiratory disturbances.

17 Additionally, if one considers the
18 potential that bruxism may serve as an early indicator
19 of possible obstruction, then it is easy to understand
20 that the use of occlusal splints may be masking a more
21 serious problem. It has been postulated that bruxism
22 may be a reflexive mechanism to splint the airway open

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1 when an obstruction is present.

2 One can easily perform a Mueller maneuver
3 and fuel the airway open in direct response to
4 clinching the teeth. The clinching or bruxism could
5 be occurring all night and is frequently seen in
6 children with large tonsils or adenoids, as well as
7 adults with OSA.

8 Although no direct correlation has been
9 demonstrated linking OSA and bruxism, it is possible
10 that this link exists. In light of these issues
11 discussed, it may be relevant for clinicians to
12 question patients about snoring, bruxism, sleep apnea
13 when recommending an occlusal splint.

14 In support of these conclusions the
15 outcomes of the 2004 joint meeting of the FDA dental
16 products and ear, nose, and throat stated that oral
17 appliances for the treatment of snoring and OSA must
18 be classified as prescription type devices due to the
19 various risks associated with the use of these devices
20 in an OTC environment.

21 Some of the risks discussed at the panel
22 meeting included can the lay person accurately self-

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1 diagnose their medical condition. Can the layperson
2 accurately self-diagnose their oral health status?
3 Can the layperson choose the correct oral appliance
4 and fit it accurately such that the device is safe and
5 effective and does not cause adverse events, that is,
6 applying forces on the teeth, tissue and temporal
7 mandibular joint?

8 These risks, as well as the outcomes from
9 research provide conclusive evidence that mouthguards
10 current classified as product code MQC should be
11 classified as prescription type devices because of the
12 potential risk associated with the fit, use, and self-
13 awareness diagnosis of the potential for OSA of the
14 person using these types of devices.

15 We agree and support the agency's ruling
16 made in the 2004 dental panel meeting to regulate
17 these devices as prescription controlled such that the
18 dental and medical profession will have oversight
19 professional intervention on the use of the device
20 such that the potential for diagnosis of sleep apnea
21 is not delayed or missed; fit the device to assure
22 successful use to minimize the potential for

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1 significant adverse impact on the airway function and
2 jaws if not properly fitted; and finally, to insure
3 safety and efficacy for patient using an occlusal
4 splint.

5 Thank you.

6 CHAIRPERSON SUZUKI: Thank you, Mr.
7 Diacopoulos.

8 The chair is going to take the prerogative
9 of recommending that we have the discussion and
10 questions on this particular presentation under our
11 open comment on OTC and NightGuards after the FDA
12 presentation. Is there any objection to that?

13 (No response.)

14 CHAIRPERSON SUZUKI: If not, then we will
15 discuss this at a later point. Good.

16 MR. DIACOPOULOS: Thank you.

17 CHAIRPERSON SUZUKI: Thank you, Mr.
18 Diacopoulos.

19 I'd like to next call on the FDA
20 presentation on the general issues of OTC use of
21 dental mouthguards.

22 Dr. Kevin Mulry.

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1 DR. MULRY: Thank you.

2 I'd like to now present on the issue of
3 whether dental mouthguards should be available as
4 over-the-counter devices.

5 This slide outlines the topics I intend to
6 discuss during my presentation. The topics include
7 the current regulatory status of dental mouthguards,
8 prescription versus over-the-counter issues, over-the-
9 counter devices, prescription devices, types of dental
10 mouthguard designs, and example of a dental mouthguard
11 design; why had dental mouthguards been cleared as
12 prescription only devices; and questions for panel
13 consideration.

14 Dental mouthguards are unclassified
15 devices. Sponsors need to submit a 510(k) or
16 premarket notification for marketing clearance. To
17 date, all dental mouthguards have been cleared as
18 prescription devices. However, some sponsors have
19 requested that these devices be made available over
20 the counter.

21 That is the reason we are asking for your
22 input today on this issue. We are asking you to

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1 discuss general issues surrounding the prescription
2 use versus over-the-counter use of dental mouthguards.

3 The discussion will include the role of the dentist,
4 the diagnosis, treatment, and follow-up to fabrication
5 and delivery of the mouthguard; the ability of the
6 consumer to self-diagnose, select, and fit a
7 mouthguard; the different designs of mouthguard,
8 including full versus partial coverage devices, the
9 types of clinical data that would be needed to support
10 an over-the-counter intended use, and the components
11 of adequate device labeling.

12 For the-the-counter use, the issue is
13 whether adequate directions for use can be written for
14 the layperson. Over-the-counter devices are available
15 for purchase directly by any layperson or consumer,
16 and for mouthguards involves the self-diagnosis of
17 one's oral health status, self-selection of the
18 appropriate device, and the correct fitting of the
19 device.

20 Over the counter devices are required to
21 have adequate directions for use for a layperson, as
22 described in the labeling section in 21 Code of

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1 Federal Regulations 801, Subpart C. If adequate
2 directions for use cannot be written for a layperson,
3 it would be considered a prescription device.

4 A prescription device -- and this is the
5 definition from a regulation -- is a device which,
6 because of an potentiality for harmful effect or the
7 method of its use or the collateral methods necessary
8 to its use is not safe, except under the supervision
9 of a practitioner licensed by law to direct the use of
10 such a device and hence, for which adequate directions
11 for use cannot be prepared, again, meaning a
12 layperson.

13 Our labeling regulations are found in
14 chapter 801 of the Code of Federal Regulations.

15 To date, FDA has cleared the following
16 type of dental mouthguards: full dental arch coverage
17 devices, which include those devices fabricated by a
18 dental laboratory, and vacuum formed or thermoformed
19 devices fitted in the dental office.

20 Also, partial dental arch coverage devices
21 that are fabricated by a dental laboratory or they are
22 prefabricated, but all of these devices have been

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1 cleared as prescription only devices.

2 This is an example of a soft, full arched
3 dental mouthguard which may have been vacuum formed,
4 thermoformed, or fabricated by a dental laboratory.

5 So why have dental mouthguards been
6 cleared as prescription only devices? Intraoral
7 devices present unique risks to dental health. They
8 are varied in design and application, and the correct
9 selection in fitting is important in preventing
10 injury.

11 Considerations for proper use include an
12 assessment of the periodontal disease, decayed,
13 missing and filled teeth, the temporomandibular joint
14 status, the origins of orificial pain, and
15 parafunctions in sorting out the various symptoms that
16 a patient may present. These symptoms may present
17 with or without pain, muscle or TMJ involvement, where
18 on the teeth, or clenching, grinding or bruxism.

19 What are the specific issues we would like
20 you, the panel, to consider today? The key
21 consideration in a determination of over-the-counter
22 use is whether adequate directions for use can be

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1 written for the layperson.

2 The following are the questions for panel
3 consideration. Question 1: dental mouthguards are
4 presently cleared for the following indications for
5 use: for protection against tooth grinding, bruxism
6 and jaw clenching that may be associated with
7 temporomandibular disorders syndrome or orificial
8 pain; also to provide short-term pain relief from
9 muscle spasm associated with occlusal interference or
10 with increased muscular activity.

11 Are any of these indications appropriate
12 for over-the-counter use?

13 Question 2: can adequate labeling be
14 written such that a layperson may diagnose their oral
15 health status, determine their need for a dental
16 mouthguard, and determine their need for a particular
17 design of mouthguard, for example, soft, hard, full
18 coverage, partial coverage, et cetera.

19 Question 3: is over-the-counter use
20 appropriate for all designs of dental mouthguards? In
21 other words, are there particular designs which would
22 not be appropriate for over-the-counter use?

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1 Question 4: of the dental mouthguard
2 design supported for over-the-counter use, please
3 recommend the following regarding the device's
4 labeling. What information should be provided to help
5 the lay user determine the need for their device,
6 ascertain the proper fitting of the device, select an
7 appropriate design, and be aware of the
8 counterindications?

9 Question 5: do you believe a clinical
10 study, that is, an actual home use study is needed to
11 support an over-the-counter indication for dental
12 mouthguards? If not, please discuss your reasons. If
13 so, please discuss the following aspects of the study
14 needed: the study design, the endpoints, and adverse
15 events that would be considered significant.

16 Thank you. I'd be happy to answer any
17 questions.

18 CHAIRPERSON SUZUKI: Okay. With respect
19 to the panel, let's take the questions one at a time
20 for open discussion. Can you reverse the slides, Dr.
21 Mulry, and begin with number one?

22 Okay. At this time I'd like to ask if

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1 there are any open comments on the OTC and dental
2 mouthguards. And there have been two requested
3 presenters, and I will call on -- well, can you
4 identify yourself, please?

5 DR. MEHTA: Yes, I will. My name is Dr.
6 Noshir Mehta, and if I can just get my slides up here,
7 I can make my presentation.

8 Thank you, Mr. Chairman, distinguished
9 panel. Thank you for allowing me to present before
10 you.

11 Let me first introduce myself. My name is
12 Noshir Mehta. I'm a periodontist. I'm Professor and
13 Chairman, however, of the Department of General
14 Dentistry through no fault of mine, and I'm Director
15 of the Craniofacial Pain Center at Tufts University
16 School of Dental Medicine.

17 I graduated from the Perio Department with
18 Irving Glickman in 1971, and I got my Master's in '73,
19 and my research from that time on has been in
20 occlusion and bruxism.

21 In 1976, I started a small craniofacial
22 pain group at Tufts, and we have grown into a fairly

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1 large and substantial group since that time. We see
2 an average of about 2,000 patients a year, new
3 patients a year, and have been doing so. We have a
4 graduate program, a postgraduate program, a Master's
5 in craniofacial pain, and we also run the clinics in
6 the predoctoral program at Tufts where students are
7 run through our program so that they understand about
8 orificial pain and both from a peripheral issue and
9 from a central nerve issue.

10 Enough about that for me. Let me just
11 state from the start that I am a consultant here for
12 Dental Concepts. They have paid me over time when
13 they have consulted me, and one of the first times
14 that I met with them was when they consulted me to
15 look at their mouthguard and also to come up with some
16 guidelines for the labeling, at which point I told
17 them that they didn't have to ask me as much because
18 all they had to do was to go to the American Academy
19 of Periodontology Guidelines for periodontal issues,
20 the orificial pain guidelines for orificial pain
21 issues, and of course, the ADA for some bruxing
22 issues.

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1 However, given that they still wanted me,
2 I have been helping them in those guidelines since.

3 I'm not going to bore you with this. I
4 respect your knowledge already. I know who you are.
5 I know some of you, but for my purposes, I need to
6 give you a reason for why I am here. I'm not just
7 here as a consultant. I am here as a practicing
8 dentist, as an educator. We have predoctoral
9 programs. We have postdoctoral programs that my job
10 is to educate these people.

11 So essentially, from past research -- this
12 is a composite of past research -- we understand that
13 tooth contacts approximately happen about 20 to 25
14 minutes in a three meal, 24 hour period. If we look
15 at forces during mastication, around the first molar,
16 which is where everybody has been evaluating that
17 because first molars approximately give us 70 percent
18 of chewing efficiency, is about 12 to 25 pounds of
19 force between the teeth.

20 If we want to be dentists here, we talk
21 about centric occlusion, centric relation, but what's
22 interesting is that centric occlusion and centric

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1 relation are about fleeting contacts, and the most
2 contacts during chewing are fleeting contacts, and
3 most of these forces that occur on these teeth from a
4 periodontal standpoint are vertically oriented forces
5 with some horizontal components, and there's minimal
6 lateral motion during chewing.

7 In fact, when teeth are contacting, there
8 is no lateral motion. The lateral motion happens as
9 the jaw opens and you have the teardrop of motion from
10 Masserman and Gibbs that was described in the early
11 '70s.

12 This was one of my first projects with
13 Irving Glickman. This was the sleep study that we
14 used to do at the time when we didn't have sleep
15 studies. This is a little box, and we had within the
16 confines of what you see here, we had a switch, an
17 oscillator, and a radio transmitter, and as contact
18 happened from the opposing tooth, there was an antenna
19 that the patient had under their pillow. This was a
20 home use program that we evaluated bruxism at the
21 time, and we found that people did clinch and grind
22 their teeth, but more often at night they tend to

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1 grind more than they clinch, and more often the
2 grinding is a lateral motion and which is one of the
3 reasons why most of us tend to see the wear patterns
4 on the canines, on the edge of the canines, which
5 means that people would have to be at that particular
6 position.

7 So eccentric positions are important in
8 parafunctional activity.

9 Tooth contacts as much as 40 minutes per
10 hour, sleep. These are some studies done by Zimmerman
11 and his group and other composites, forces
12 approximately 150 kilograms to 300 pounds. Single
13 contacts may be as long as nine seconds, horizontal
14 and vertical forces and side-to-side rocking action,
15 and this becomes important as we will see later.

16 I've heard a lot about the etiologic
17 theories and the issues that are here in terms of
18 whether or not it's an occlusal issue. I think we've
19 all laid that to rest for the most part at this point.

20 The issues were originally then psychological. I
21 think we're starting to find that psychological issues
22 are not really as important as they were, and some of

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1 those patients that we've been sending for constant
2 biofeedback don't have to necessarily be there.

3 We talk about systemic and sleep, and I'd
4 like to just mention those two a little bit more in
5 detail because of the conversation that has been going
6 around. These are my own ideas and my own thoughts,
7 but with the past history of seeing a lot of these
8 patients.

9 Bruxism has been in evidence since the
10 beginning of time. We all know that. If we look at
11 the literature, everybody starts with "bruxomania" as
12 the terminology, and common things happen commonly,
13 and I think that's the most important thing that we
14 need to remember when we talk about these issues.

15 Most people don't die in their sleep
16 because of bruxism. Most people don't die in their
17 sleep because of neurologic problems. These people
18 are very few and very far between. Yes, it's
19 important for us to understand that, but even now,
20 even now, we're just starting into sleep disorders.

21 We at the center also work with the sleep
22 disorder team, and I know that panel members here are

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1 well versed in sleep disorders.

2 So my point is: let's not lose sight of
3 what is the big issue. The big issue is that people
4 grind their teeth. Grinding of the teeth doesn't
5 necessarily mean they have sleep disorders. Grinding
6 of the teeth doesn't necessarily mean they have
7 temporomandibular joint disorders.

8 In fact, the American Academy of Orificial
9 Pain in their guidelines have stated, and if I may,
10 Mr. Chairman, I'm going to just read that guideline to
11 you, that statement that they came up with because I
12 don't know if you have that in front of you. This is
13 the orificial pain guidelines for assessment,
14 diagnosis, and management, the American Academy of
15 Orificial Pain in 1996. The editor was Dr. Oakison
16 (phonetic) that we all know.

17 "Parafunction habits such as teeth
18 clinching, tooth grinding, lip biting and abnormal
19 posturing of the jaw are common and do not usually
20 result in TMD symptoms. The most commonly believed
21 indication of past nocturnal severity is dental
22 attrition."

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1 That's what we see. That's what I see in
2 my patients. That's what we see as dentists.

3 the question about systemic disorders,
4 yes, we now do see people who have neurologic
5 disorders who can also grind, but the bruxism in those
6 situations is extremely severe. It's a different
7 variety, and these people have already been diagnosed
8 by many times as having a neurologic disorder because
9 usually these people have other disorders that have
10 been picked up in early childhood as genetic factors,
11 as later when they see their primary care physicians.

12 Usually these patients come to me. They're sent by
13 their primary care physician because they know they
14 have a problem, and they're sent to us because they
15 think we need a soft guard between their mouth.

16 And so we do use soft guards. We use a lot
17 of soft guards in our patients. So soft guards by
18 themselves are not an issue.

19 The third part of this is the sleep issue
20 that the company from Respiroics has just mentioned,
21 and I think it's a great company. In fact, I have
22 relationships with some of the people who use

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1 Respironics, but here's my issue with that also.

2 We have been told, we have been told that
3 -- and I should get this for a second -- we have been
4 told that there is a study out there by Gene Levigne
5 from Toronto, and I know of him, and I know that he is
6 an excellent researcher, but I think it would be
7 unwise -- I think it would be unwise to just look at
8 that one study as a decision making process.

9 This is the beginning. This is the
10 beginning of what we know about sleep disorders. We
11 are at a very infant stage for us to make judgments on
12 sleep disorders and their relationship to what we do.

13 This particular study that was reported,
14 was a study that came out from their group in Toronto
15 in July and August, and it came in the International
16 Journal of Prosthodontics, and I think it has been
17 accurately reported. So I don't have an issue with
18 the actual reporting of it.

19 What I do have an issue is that what has
20 not been reported is a study that the same group came
21 up with in May of 2004 that is just one month,
22 actually two months before that, and where they looked

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1 at the quantitative, polygraphic control study on
2 efficacy and safety of oral splint devices in tooth
3 grinding subjects, and this was published in the
4 Journal of Dental Research in May of 2004.

5 I can leave you with the actual reference
6 after this talk.

7 The study that has been reported were on
8 ten subjects. The study that was reported, this one
9 that I'm telling you is nine subjects. So far we've
10 got 19 subjects reported, hardly a large population
11 with which to make decisions.

12 But in this particular study nine subjects
13 were looked at with sleep bruxism to compare the
14 safety and efficacy of an occlusal splint with a
15 palatal control device. So there were two devices.

16 The baseline was sleep laboratory data on
17 the second night, followed up one night later,
18 followed up for one night on week three and one night
19 on week four. So there were three sleep studies done.

20 One was a baseline, one was one week alter on week
21 three and one week alter on week four, three nights.

22 What they found was there was a

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1 statistically significant reduction in SB, which is
2 sleep bruxism, bursts per hour by 41 percent and 40
3 percent observed with both appliances, the appliance
4 that was the palatal control device and the occlusal
5 splint.

6 Both showed 50 percent fewer episodes of
7 grinding noise. No changes in respiratory variables
8 were observed between the two devices, and both
9 reduced muscle activity associated with sleep bruxism.

10 So I take you to these two studies done at
11 the same laboratory reported one and a half months
12 from each other. You can decide which one do you
13 prefer to use, but the fact of the matter is that the
14 jury is not in as to what appliances can and can't do
15 yet with bruxism, with sleep bruxism.

16 As far as the self-reporting is concerned,
17 having been in this business of bruxism for a long
18 time, the only thing I can report to you is that when
19 I have a patient who tells me that grinding their
20 teeth is what I consider active and present bruxism,
21 if I look at one teeth, that may or may not be active.
22 It may or may not be present. If I look at any other

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1 criteria, that does not necessarily mean that they're
2 grinding their teeth.

3 People how have temporomandibular
4 disorders don't always grind their teeth. We've seen
5 that. It's written again in the Annals of the
6 American Academy of Orificial Pain. People who grind
7 their teeth may have pain, but they may not have pain.

8 So, again, pain is not a factor that you
9 can accurately depict bruxism. The only thing that I
10 know as a dentist, the only way I can tell whether or
11 not somebody really needs a guard from my standpoint
12 is if the patient tells me, "I'm grinding my teeth
13 every night. My wife wakes me up in the morning and
14 tells me I've been grinding my teeth. She kicks me
15 out of bed because she doesn't want me in bed."

16 Those are the types of things that I take
17 a look at and say, okay, there is active bruxism in
18 this patient. So self-reporting, unfortunately, at
19 this present moment is the primary source by which the
20 dentist can look at bruxism.

21 Can they look at bruxism differently?
22 Yes. We have sleep studies, but how many patients who

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1 come into your practices are you going to send for
2 sleep studies to tell them that they grind their teeth
3 or they don't grind their teeth.

4 So right now as we stand, once we come
5 up -- and they are coming up with these things -- once
6 we come up with more home recording units for sleep,
7 then maybe we can use those to look at bruxism a
8 little bit more effectively. But presently as it
9 stands there are not that many sleep labs out there.
10 They don't have that many beds. You can't send
11 everybody who grinds their teeth to a sleep lab to
12 make sure that they grind their teeth.

13 So what can we do? Again, as a dentist, I
14 provide a mouthguard. I provide a mouthguard, and
15 it's one at night, and what am I trying to do? I'm
16 trying to just keep the teeth away from each other.

17 Now, the question then comes in, well,
18 when you provide a NightGuard, whether it's an upper
19 or a lower and a single guard, and I know that it has
20 been touched on here, the jaw drops back. It doesn't.

21 I can tell you that the jaw doesn't necessarily drop
22 back unless the patient happens to be lying flat on

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1 their back all night long.

2 Now, why do we think that people lie flat
3 on their back all night long? I can guarantee you
4 I've done this with other groups. I can guarantee you
5 that most of us don't sleep on our backs all night
6 long. Most of us turn to one side or the other.

7 And so the question is when remarks are
8 made without evidence that this happens, it bothers me
9 because as a dentist I'm supposed to be providing
10 treatment for patients, and now I have to tell them
11 why, you know, you can't have mouthguards because
12 mouthguards may cause your jaw to drop back and you
13 may die in your sleep.

14 Well, I haven't seen any evidence of that.
15 I've seen a lot of patients over many years, a lot of
16 my colleagues, and interestingly enough, it's where
17 you go.

18 When I go to the temporomandibular
19 disorders programs, everybody complains that sleep
20 devices are causing TMJ problems because you're
21 bringing the jaw forward and you're causing damage and
22 the teeth are not going to fit after that.

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1 Do I believe that? Of course, not, but
2 the fact of the matter is you hear what you hear when
3 you go to the people who are saying what they're
4 saying only because that's what is the program for
5 that day.

6 So, please, I think you need to be a
7 little bit more evidence based, and I am hopefully,
8 knowing all of you who are in research and who are on
9 this panel, that you are evidence based. So I'm going
10 to try to bring and keep this to an evidence based
11 system rather than, you know, using our hearts and not
12 our heads.

13 So what are the types of mouthguards? And
14 Dr. Mulry has already mentioned many different kinds,
15 but what am I here for today? I'm not here to sell
16 you hard guards. I'm not here to sell you what the
17 dentist does. I'm not here to sell you what the
18 laboratory does. I respect all of that. I know that
19 most dentists are very attuned to putting in guards.

20 But I am here to tell you that there are
21 some guards out on the marketplace that people who
22 cannot afford you and me will need, and I think that

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1 those need to be out there, and I'm not saying this
2 because I'm a consultant here today for Dental
3 Concepts. I'm just telling you this because that's
4 the fact of the reality.

5 I can't tell you how many E-mails I get
6 that say, "Dr. Such-and-such, you know, I live in
7 Idaho and I went to the dentist and I can't afford the
8 appliance and they've told me that I need something.
9 What should I do?"

10 I tell them to go to the pharmacy and pick
11 up a guard. It's better than not. It's better than
12 not.

13 So, again, I'll come back now and I'll
14 come back to what we were talking about this morning,
15 and the boil and bite technology. Why do I like this?

16 Well, I'll tell you why I like this. It's something
17 that you are giving these patients. You're giving
18 them some ability to control their own life.

19 They're not stupid. Consumers are very,
20 very good. They go on the Internet. They know what's
21 going on. They're not stupid. Let's not consider
22 them that way.

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1 Soft plastic molds to the shape of teeth
2 and then it hardens. Now, there was a good question
3 from the panel that said is it a hard or is it a hard
4 and soft. Well, in this particular instance, the boil
5 and bite technology we're talking about has a soft
6 inner site and a slightly harder outer site, and what
7 it does for us is it allows the person -- because, you
8 know, when you pick out a boil and bite guard from a
9 boiling pan, you don't want to touch it, and so the
10 lower part of that guard is less hard. It doesn't
11 fold on itself, which happens when people try to do
12 that, and it allows a nice, simple fit.

13 And it is a simple fit. It is easy for
14 consumers to use, and currently it's widely available.

15 Again, I did a Medline search. I knew I
16 was coming before you. I knew you were an evidence
17 based panel. I said I need to find out how much
18 damage is out there.

19 I did a Medline search, and it was
20 interesting. This was my situation with my graduate
21 students. I had them search for it. I had the
22 librarians at Tufts search for it, and I searched for

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1 it myself. I couldn't find anything. I couldn't find
2 anything.

3 And, in fact, I couldn't believe that I
4 couldn't find anything because to me that's almost
5 impossible. In dentistry, any time you want some
6 adverse effects, you'll find it somewhere, in some
7 little area hidden away. But I couldn't find it.

8 What did I find, however? Sports
9 injuries, but these sports injuries were using soft
10 guards in sports and getting injured by sports, not by
11 the soft guard. The soft guard wasn't protecting
12 them, but this particular guard is not designed for
13 sports. That's a totally different kind of guard, and
14 I want to make sure that we don't confuse this part.

15 So as I understand it, these are the three
16 basic things that I as a dentist would like to know.
17 Consumers must be able to determine if they need the
18 product. The directions for the use must be
19 understandable, and my now having read up on all of
20 this, apparently it's also an eighth grade level, and
21 consumers must be able to know when to consult a
22 dental profession because I do want to make sure that

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1 if we put something out on the marketplace people
2 don't injure themselves. I don't want to change the
3 past history of no injuries to suddenly having a lot
4 of injuries.

5 Consumers must be able to determine if
6 they need the product. Now, most bruxers, if you're
7 only giving it for bruxism, will tell you that they
8 grind or their bed partners are going to kick them out
9 of bed and tell them they grind, and they will likely
10 seek a product to prevent teeth from making contact.

11 If they don't know that they grind,
12 they're not even going to look for a product. So the
13 point is moot. I mean the only way they will go for a
14 product is if they think they grind their teeth and
15 the only way they know that is if somebody tells them
16 or they know for sure because they wake up with tooth
17 grinding.

18 So if they don't know this, and that's a
19 question of diagnosis, can they diagnose bruxism?
20 Well, if they don't know it, they're not going to go
21 looking for it.

22 Directions of use must be understandable.

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1 I think that millions of units, not just of the units
2 that we're talking about here, but millions of units
3 in athletic mouthguards and stuff use the same
4 technology. So the technology has been out there.
5 It's not that difficult.

6 Children fit themselves. Parents of
7 children fit the children, and a lot of people as we
8 now have used guards at night and they fitted
9 themselves.

10 So the question is: what happens if it
11 doesn't fit? Well, what happens if I give a guard to
12 a patient and it doesn't fit? They don't wear it.
13 They don't wear it. Do you know why? Because they
14 can't wear it.

15 So the question is if it fits, does it fit
16 well enough. Well, those are the questions that if
17 the patient is wearing it, then the fit is reasonable
18 for that particular patient. So I'm not sure that the
19 fit aspect of it is a big factor, but anyway, I will
20 go along with making sure that the fit should be
21 adequate and controlled.

22 They should know when to consult a dental

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1 professional. Now, you've been given a sheet this
2 morning from the Dental Concepts people regarding the
3 labeling, and I would suggest that the labeling is
4 very detailed. It tells the patient when not to use
5 it. It tells the patient when to ask the dentist
6 before they use it, and then it also tells the patient
7 when not to use it and go to the dentist.

8 So I am a little proud of this label only
9 because I was associated with the development of it,
10 and the development of it I took directly from the
11 academies that I belong to, the American Academy of
12 Periodontology and the American Academy of Orificial
13 pain, and of course, the ADA.

14 So my feeling was that this would protect
15 people. This would protect people sufficiently, and
16 we may have our arguments and differences, but you
17 have to give me that. You have to give me the fact
18 that if the academies think that this is a reasonable
19 question to ask a patient for self-report mechanisms,
20 then they must have spent many hours, many committees
21 to come up with those questions, and I wasn't about to
22 change that.

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1 So I asked the company when they came that
2 those are the questions I wanted in there because
3 those were the questions I felt that had been vetted
4 by the appropriate academies.

5 So --

6 CHAIRPERSON SUZUKI: Can you conclude, Dr.
7 Mehta?

8 DR. MEHTA: Yes, I will immediately.

9 So the question is in terms of can
10 adequate directions for use be written such that lay
11 people may be able to diagnose their oral health.
12 They're not diagnosing oral health here. We're just
13 diagnosing bruxism. We're not diagnosing. We're not
14 asking people to be able to tell us if they have oral
15 health conditions because I don't think they can do
16 that.

17 But I do think that people can tell you
18 when they grind the teeth.

19 On Question 2, if OTC use is supported,
20 are there any designs or types? I do think that full
21 coverage appliances make the most sense. As a
22 dentist, I sometimes will use a partial cover

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1 appliance, but I need to be monitoring that. So if
2 somebody is not monitoring I think full coverage
3 appliances make the most sense.

4 Of the dental mouthguard design supported
5 by OTC use, please recommend -- I'm sorry. You have
6 the label in front of you. I don't have to go into
7 details about that.

8 And then the last part is: do you believe
9 a clinical study is needed? You know, because I'm a
10 dentist and I teach at Tufts and we live and die by
11 research, of course I would always say clinical
12 research should be done.

13 However, in this particular case, I think
14 that there's no evidence to show that we need a
15 clinical project. There's no evidence to show that
16 there's actual problems with these guards in the past.

17 Certainly if you want to do a clinical project what I
18 might suggest is looking at the labeling and seeing if
19 the label can be followed and looking at the fit
20 because once it's well fit and once the label is
21 accurately followed, I don't think these guards are
22 unsafe. I think that in my conclusion to you, I would

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1 very much like for you to consider that there are
2 patients out there who can't afford dentistry for
3 whatever reasons. They need something to help protect
4 them. It's unfair for them, and I think it
5 prevents -- this sort of a guard prevents the teeth
6 from touching for bruxism. It is easy and it is safe.

7 Thank you for listening to me.

8 CHAIRPERSON SUZUKI: Okay. Thank you, Dr.
9 Mehta.

10 I would like to next call on Respironics,
11 who submitted a statement, and then we can open
12 pointed questions and discussion from the panel.
13 Okay. The next presenter?

14 It's the same one. So you can just --
15 okay. So then we can have questions and discussion
16 from the panel to both presentations, and then FDA's
17 presentation also through questions.

18 Ms. Howe.

19 MS. HOWE: Dr. Mehta, I'd like to thank
20 you for being an incredible consumer advocate, and
21 though we are, in fact, an evidence based panel, I
22 think it is important to remember what you said about

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1 common things happening commonly, and to address this
2 with common sense.

3 Thank you very much.

4 DR. MEHTA: Thank you.

5 CHAIRPERSON SUZUKI: Other questions? Dr.
6 Zuniga.

7 DR. ZUNIGA: Yes. Dr. Mehta, would you
8 agree then that one of the statements we're asked to
9 determine here is under cleared for the following
10 indications that you would agree that there's no
11 indication that these OTC mouthguards could be
12 adequately used for short term pain relief?

13 DR. MEHTA: That's not what this
14 particular guard is. There are guards out there, for
15 instance, the guard that's already out there from this
16 company is usually used for soft, short pain relief.
17 A patient goes in to see the doctor, and I use them
18 actually a lot because what happens is patients come
19 in on an emergency, as I'm sure they come into your
20 offices, too. You know, you don't want to take an
21 impression because the jaw is hurting. So we just
22 take this boil and bite, put it in, soak it, and have

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1 the patient bite on it, and after a few days or maybe
2 even a week come back and it will give us time to go
3 on and see what else is needed.

4 I think most people have now decided that
5 short-term use with a soft guard is actually very
6 good. In an article that was written by Steve Messing
7 in the sales book on temporomandibular disorder that
8 Kaplan in Cell, they suggest that the use of a soft
9 guard as a predictor of the use of a hard guard, that
10 when those soft guards were used before the hard
11 guards actually worked even better, to 93 percent
12 success.

13 CHAIRPERSON SUZUKI: Thank you.

14 Other questions, comments? Any questions
15 on the FDA presentation for Dr. Mulry?

16 (No response.)

17 CHAIRPERSON SUZUKI: If not, thank you.

18 DR. MEHTA: Thank you, sir.

19 CHAIRPERSON SUZUKI: I'll ask Dr. Mulry to
20 come up and put the questions on the screen once
21 again.

22 Okay. I'd like to begin with Question No.

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1 1. Dental mouthguards are presently cleared for the
2 following indications for use: for protection against
3 tooth grinding, bruxism and jaw clenching that may be
4 associated with TMD syndrome, orificial pain; to
5 provide short-term pain relief from muscle spasm
6 associated with occlusal interference or with
7 increased muscular activity.

8 The question FDA is asking the panel: are
9 any of these indications appropriate for OTC use?

10 Dr. Bakland?

11 DR. BAKLAND: You know, with the labeling,
12 would it be reasonable for the labeling to use a
13 measure such as pain as being the way to decide for
14 the patient to buy this mouthguard or not? In other
15 words, if the labeling clearly stated that if you have
16 pain you need to see a dentist, that these are not
17 appropriate for orificial pain?

18 CHAIRPERSON SUZUKI: Okay. Is there a
19 comment on that, follow-up?

20 Other questions? Dr. Demko.

21 DR. DEMKO: I just want in mentioning what
22 we're looking at, it says protection against tooth

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1 grinding. As far as I can tell, it's really
2 protection against the damage from tooth grinding,
3 that you're still going to brux; that what we're
4 trying to prevent is damage to the teeth, and perhaps
5 the lack of noise.

6 When you're looking at something where
7 it's mechanical versus I agree with Dr. Bakland that
8 if there's anything with pain involved, and these
9 comments that have been already given out by the
10 company very clearly say that if there's any pain or
11 clicking or jaw noises don't use this or ask your
12 dentist first.

13 Probably an indication for appropriate OTC
14 use. My biggest concern is I don't want the FDA to
15 lose control over these, that as time goes on we find
16 more things that may be related to bruxism as medical
17 disorders; that their control should still be under a
18 510(k).

19 CHAIRPERSON SUZUKI: Okay. Any other
20 comments? Dr. Zero.

21 DR. ZERO: Yes, I need a point of
22 clarification between the currently available athletic

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1 mouthguards and the physical structure and this other
2 application, which would be to prevent bruxism or to
3 prevent the damage of bruxism. Is the material
4 significantly different?

5 CHAIRPERSON SUZUKI: Okay. Dr. Mehta, can
6 you respond?

7 DR. MEHTA: Yes, I can. It is
8 significantly different in the sense that a mouth
9 protector such as a sports car has a flange, a hard
10 flange that goes across the upper front teeth and
11 along the upper side teeth. This does not. This is
12 not designed for that, and it's one of the reasons why
13 in the labeling you see -- and I was quite adamant
14 that it be put in there as not being used as a mouth
15 protector.

16 DR. ZERO: In your experience, do patients
17 who come to see you -- are some of them using athletic
18 protectors to prevent bruxism?

19 DR. MEHTA: There are some athletic
20 protectors out there that are sold as athletic
21 protectors without that coverage, and so I don't know.
22 They don't actually come to see me because if they

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1 come to see me, they come really for the TMJ stuff.
2 We don't see kids, and we don't do athletic guards
3 yet.

4 DR. ZERO: And the reason I'm raising this
5 is because I'm trying to get at this issue. Is it
6 better to leave something unregulated because the
7 practice is that people will tend to do these things
8 anyway versus classify it and have something as a
9 Class I device that they can use more appropriately,
10 and then there can be some oversight by the FDA
11 because it's used for this application.

12 Do you understand the --

13 DR. MEHTA: Yes, I do, and I appreciate
14 your sentiments. The issue is right now there are
15 many guards out there that people are using as
16 athletic mouthguards. If you go to Sports Authority
17 or places like that, you'll see 15, 20 from different
18 companies.

19 DR. ZERO: No, I'm not going that way.
20 I'm going more that people are using those types of
21 products for this application that we're discussing
22 today.

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1 DR. MEHTA: Most athletic guards have a
2 hard shell. That's the difference between the regular
3 mouthguard and an athletic guard. Now, I don't know
4 the answer that you're asking me, which is would
5 somebody use it. I suppose anybody can do whatever
6 they wish to do, but the fact is that if they're going
7 for an athletic guard, they're going to go to a sports
8 store or they're going to go to -- so they'll end up
9 at something that whether it's actually the best for
10 them or not, they'll end up with something that has a
11 hard shell in front.

12 DR. ZERO: Thank you.

13 CHAIRPERSON SUZUKI: Other questions?
14 Yes, Dr. O'Brien.

15 DR. O'BRIEN: I think the main issue
16 here -- it's been discussed in the presentation -- is
17 the criticalness of the fit. Fit isn't a very simple
18 item with these devices, as with fitting shoes or
19 other articles of clothing. There's a whole science
20 of articulation and occlusion, which is an advanced
21 subject in dentistry, and it involves not only the fit
22 of the mouthguard over the teeth, but how the

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1 mouthguard articulates in occlusion with the other
2 arch of the mouth.

3 And it is a difficult job to have a good,
4 successful mouthguard under a dentist's care. It is a
5 challenge, and many dentists use several different
6 articulators, and often I've observed that it takes
7 hours for the dentist to finally get the final
8 articulation of the mouthguard working with the
9 patient in the chair, and it is a great stretch of the
10 imagination without clinical evidence that you can
11 obtain and use an over-the-counter device that the
12 patient can use following directions, achieving
13 appropriate articulations so that it's comfortable and
14 correct for the patient.

15 However, it's also true, and I agree with
16 the speaker, there isn't much evidence of complaints
17 about these mouthguards. However, if you talk to the
18 people that run clinics for athletic mouthguards,
19 they'll tell you if they're not correct, the athletes
20 just don't use them.

21 So that you can have no complaints and
22 everyone seems to be happy, but if you don't have use

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1 of the device, it is failing in its efficacy in terms
2 of solving the problem, which is to protect the teeth
3 from damage during athletics.

4 So that a study needs to be done in terms
5 of how well these fit in articulation and also what
6 the compliance is by interviewing enough athletes in
7 terms of using the over-the-counter mouthguards, and I
8 don't see any clinical evidence in that regard. If
9 there is, I'd like to hear about it.

10 CHAIRPERSON SUZUKI: Okay. Dr. Mehta, did
11 you want to respond?

12 DR. MEHTA: I would for two reasons. One
13 is -- and I absolutely agree with Dr. O'Brien -- one
14 of the issues is that we are talking about hard
15 guards. When dentists try to fit hard guards, and
16 this is an issue that we teach our students also, they
17 send them to the laboratory. The laboratory
18 manufactures them based on models that have been
19 articulated.

20 The patient comes in. The model and the
21 guard is brought in. These guards are usually too
22 thick, which is why we never send any of ours out to a

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1 laboratory, other than orthodontic type ones or ones
2 that we think they're separate types.

3 We use certain articulators. Articulators
4 are not the same as the jaw, and so function in the
5 mouth, you have to when it's a hard guard, you have to
6 adjust it regardless of what else you do. So I agree
7 with you that there is adjustment, which is the real
8 reason that most general dentists, a lot of general
9 dentists in my neighborhood at least in Boston,
10 Massachusetts, use soft guards, because they don't
11 want to sit there adjusting them, and they actually
12 send the soft guard to the lab. They put it in the
13 patient's mouth and say, "See you later. Call me.
14 You know, call me if there's a problem."

15 So the reason they go to the soft guards
16 is because it prevents them from having to do just
17 what you're talking about, and that's one of the
18 reasons why a hard guard is not something that you can
19 put out directly to a consumer because it does require
20 that.

21 And we're not talking about sports guards
22 here. We're just talking about the guards for

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1 bruxism.

2 CHAIRPERSON SUZUKI: Okay. Other
3 comments?

4 MS. HOWE: He clarified my point. Thank
5 you.

6 CHAIRPERSON SUZUKI: Okay. Thank you.

7 Other questions or comments regarding this
8 question?

9 DR. O'BRIEN: I have another comment.

10 CHAIRPERSON SUZUKI: Dr. O'Brien.

11 DR. O'BRIEN: Based on the previous issue
12 in which the panel was asked whether or not this
13 device if not used would cause permanent damage, and I
14 voted use because if you have seen mouths of patients
15 that have had severe bruxism, there's a great deal of
16 loss of enamel and especially with the lower arch, the
17 lower front teeth. We have very few restorative
18 procedures for restoring the appearance and function
19 of the enamel being lost due to bruxism from lower
20 front teeth. So it does do permanent damage on a wide
21 scale, unless it's caught in time, hopefully by the
22 practicing dentist of the patient.

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1 CHAIRPERSON SUZUKI: Okay. Thank you.

2 Dr. Mehta, would you like to respond?

3 DR. MEHTA: If you look at the labeling
4 that you have in front of you, it's again in there.
5 It says stop use and ask a dentist if your original
6 symptoms persist even after several weeks of use. The
7 product usually falls out of your mouth. It causes
8 you to gag or otherwise feel uncomfortable if you
9 experience shifting or loosening of your teeth or any
10 of those things.

11 So we've tried to accommodate these
12 thoughts into I thought as best a label as we could
13 come up with. So hopefully anybody who is
14 understanding of the label would be able to say, "I'd
15 better go see the dentist."

16 CHAIRPERSON SUZUKI: Dr. runner.

17 DR. RUNNER: I just want to remind the
18 panel that this isn't about just one product. So your
19 recommendation should apply to all products that would
20 potentially be over-the-counter.

21 CHAIRPERSON SUZUKI: Okay. Thank you.

22 Okay. Dr. Bakland.

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1 DR. BAKLAND: I don't know if as a
2 consultant whether I can make a recommendation or not,
3 but if I can do it as a consultant.

4 CHAIRPERSON SUZUKI: Certainly.

5 DR. BAKLAND: I would recommend that for
6 this particular issue, that the indications would not
7 be appropriate as a whole for over-the-counter use.
8 The only indication here that would seem reasonable
9 based on what has been presented would be clearly
10 bruxism.

11 CHAIRPERSON SUZUKI: Okay. Then why don't
12 we pose the first question then and go around the
13 panel and get your individual suggestions.

14 Question No. 1, once again, dental
15 mouthguards are presently cleared for the several
16 indications. They are listed on the screen. Are any
17 of these indications appropriate for OTC use?

18 I'll begin first with Dr. Cochran.

19 DR. COCHRAN: I think we can can bruxism
20 and tooth grinding.

21 CHAIRPERSON SUZUKI: Okay.

22 DR. COCHRAN: I'm not sure what the

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1 definition of tooth grinding is different from
2 bruxism. That's my problem there.

3 CHAIRPERSON SUZUKI: Okay. Dr. O'Brien.

4 DR. O'BRIEN: The question specifically
5 relates to over-the-counter?

6 CHAIRPERSON SUZUKI: Are any of these
7 indications appropriate for OTC use?

8 DR. O'BRIEN: No, I don't think so because
9 of the problem in obtaining the correct fit by an
10 amateur patient who doesn't know how to evaluate that.

11 CHAIRPERSON SUZUKI: Okay. Dr. Zero.

12 DR. ZERO: Given the history of no
13 documented problems, I think I am comfortable with the
14 idea of having the first indication protection against
15 tooth grinding and bruxism for OTC.

16 CHAIRPERSON SUZUKI: Dr. Zuniga.

17 DR. ZUNIGA: I would vote, yes, that there
18 are indications for OTC use for bruxism only. I do
19 have concerns about tooth grinding as it's difficult
20 to determine by the patient or self-diagnosis or the
21 help of their partner. I don't think occlusion or fit
22 is a real serious problem with this type of device.

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1 There are evidence based studies that I believe even
2 if you remove the occlusal surfaces that you will have
3 positive responses. So it's less of a problem for the
4 short-term uses.

5 CHAIRPERSON SUZUKI: Okay, and the
6 industry representatives. Ms. Howe.

7 MS. HOWE: I would recommend both tooth
8 grinding and bruxism, maybe exactly the opposite of
9 what you were saying, Dr. Zuniga. I think the
10 consumer needs to have the tooth grinding as more of a
11 vocabulary term as opposed to Bruxism.

12 CHAIRPERSON SUZUKI: Mr. Schechter.

13 MR. SCHECHTER: I would agree that I think
14 it's appropriate for Bruxism and tooth grinding.

15 CHAIRPERSON SUZUKI: Dr. Bakland.

16 DR. BAKLAND: Yes, bruxism I'm in favor
17 of, and in terms of the wording "tooth grinding," I
18 think in one of the presentations earlier, the term
19 "gritting" was used, and you know, not having been
20 brought up with the Queen's English I'm not sure if I
21 know the differences between gritting and grinding,
22 but just intuitively I think of gritting as something

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1 that a layperson would understand better than tooth
2 grinding.

3 So perhaps we should consider using the
4 term "gritting" since that already has been introduced
5 here.

6 CHAIRPERSON SUZUKI: Okay. Dr. Demko.

7 DR. DEMKO: Just going back to gritting,
8 clenching and bruxism are actually different as far as
9 I've read the literature, and clenching puts much more
10 severe sustained forces on the teeth, and that would
11 be gritting; that I would not be as happy about
12 putting appliance out there for clenching as an OTC
13 situation.

14 However, I think that for bruxism
15 patients, complaints of acute bruxism, short-term use,
16 OTC possibly, but for anything else that's dealing
17 with pain or TMJ, absolutely not.

18 CHAIRPERSON SUZUKI: Okay, and we're not
19 taking a vote on this. We're just making the
20 recommendations.

21 Dr. Mulry.

22 DR. MULRY: Yes. I was just wondering

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1 whether we could have a clarification. Are you
2 talking about bruxism with pain or without pain? Can
3 you just make that distinction for us?

4 I think that would be helpful because
5 we've had a discussion here whether pain is important
6 in looking at whether an over-the-counter indication
7 is appropriate.

8 DR. DEMKO: Because basically I would
9 believe if there's any pain involved then it shouldn't
10 be OTC. It should be people who are just complaining
11 of the noise, but not if there's pain because now
12 you're getting into TMJ and muscle problems, and that
13 is not what I would consider an OTC use of any
14 appliance.

15 CHAIRPERSON SUZUKI: Okay. Does FDA
16 require any further information on Question No. 1?

17 MS. RUNNER: Just if you might poll the
18 panel on that question that would be helpful.

19 CHAIRPERSON SUZUKI: Okay. So, Dr.
20 Runner, in particular about the pain associated?

21 DR. RUNNER: Correct.

22 CHAIRPERSON SUZUKI: Okay. Let's poll the

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1 panel just with respect to that question on if pain is
2 associated, then it should not be OTC.

3 Dr. Cochran?

4 DR. COCHRAN: Yes, I agree with Dr. Demko
5 exactly. If pain is involved it's not OTC.

6 CHAIRPERSON SUZUKI: Dr. O'Brien?

7 DR. O'BRIEN: I agree.

8 CHAIRPERSON SUZUKI: Dr. Zero.

9 DR. ZERO: I agree.

10 CHAIRPERSON SUZUKI: Dr. Zuniga.

11 DR. ZUNIGA: I agree.

12 CHAIRPERSON SUZUKI: Ms. Howe.

13 MS. HOWE: I believe it could still be OTC
14 if it's in the recommendations to check with your
15 professional if, and then put in if there's pain
16 involvement.

17 CHAIRPERSON SUZUKI: Okay. Mr. Schechter.

18 MR. SCHECHTER: I agree.

19 CHAIRPERSON SUZUKI: Dr. Bakland.

20 DR. BAKLAND: Bruxism without pain.

21 CHAIRPERSON SUZUKI: Dr. Demko.

22 DR. DEMKO: Bruxism without pain.

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1 CHAIRPERSON SUZUKI: Okay. To summarize
2 that particular point then, it appears that if pain is
3 associated, then it should not be OTC.

4 And in addition, overall bruxism, quote,
5 tooth grinding, gritting, clinching if I'm not
6 mistaken, did I cover all the bases? That would be
7 indications for OTC use.

8 DR. COCHRAN: I don't believe clinching
9 was involved in that. Only bruxing and patient's
10 tooth grinding maybe.

11 CHAIRPERSON SUZUKI: Okay. To further
12 clarify, bruxism and tooth grinding.

13 Okay. Does FDA have any further
14 clarifications?

15 Okay. Do you want to put up Question No.
16 2 please? And while Dr. Mulry is doing that, I'll
17 read the question. Can adequate labeling be written
18 such that a layperson may question any of the items
19 listed on the screen?

20 And I will poll the panel and get a
21 viewpoint beginning with Dr. Cochran.

22 DR. COCHRAN: I don't believe that the

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1 patients can diagnose their oral health status. I do
2 think they can determine their need for a mouthguard
3 if they're making noise with their mouth at night, and
4 I do not believe that they can determine what design
5 is best for them.

6 CHAIRPERSON SUZUKI: Okay.

7 CHAIRPERSON SUZUKI: Okay. Dr. O'Brien.

8 DR. O'BRIEN: I also don't agree, and very
9 often bruxism is picked up unintentionally by a
10 dentist during a routine exam where they noticed that
11 the teeth are being worn away.

12 CHAIRPERSON SUZUKI: Dr. Zero.

13 DR. ZERO: I also agree that a layperson
14 cannot make a diagnosis, but I do agree that they can
15 determine the need for a NightGuard.

16 CHAIRPERSON SUZUKI: The design?

17 DR. ZERO: In terms of the design, I think
18 that's sort of the next question in the way of, you
19 know, how far to go with the OTC approval and what
20 types of designs will be included. So I don't think
21 patients can choose the right kind. I think we have
22 to be maybe prescriptive at our level of approval.

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1 CHAIRPERSON SUZUKI: Okay. Dr. Zuniga.

2 DR. ZUNIGA: I agree that patients cannot
3 generally diagnose their own health status, but I
4 agree that they would be able to identify bruxism, and
5 I disagree that they would be able to determine the
6 type of full coverage versus partial coverage.

7 CHAIRPERSON SUZUKI: Okay.
8 Representatives from industry, Ms. Howe.

9 MS. HOWE: Perhaps the terminology of
10 "oral health status" is the stumbling block. I think
11 consumers can certainly identify their need to have
12 some protection against grinding, and certainly there
13 need to be products available to people considering
14 the numbers of people who have grinding problems as
15 compared to the major problems which would indicate a
16 need to see a professional, cracked teeth, pain, those
17 kinds of things.

18 I think they could determine their need
19 for a mouthguard by trying the mouthguard to see if
20 that would relieve the problem.

21 CHAIRPERSON SUZUKI: Okay. Thank you.

22 Mr. Schechter.

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1 MR. SCHECHTER: I certainly think the
2 public can diagnose bruxism if they're conscious of
3 it. If they're not conscious of it, they're not going
4 to go seek one of these products anyway. So I don't
5 think that's an issue for the OTC indications that
6 we've approved.

7 Similarly, I think they can determine
8 their own need for a mouthguard, but I agree that they
9 probably can't determine which design would be best
10 for them.

11 CHAIRPERSON SUZUKI: Okay. Dr. Bakland.

12 DR. BAKLAND: I don't believe they
13 probably can diagnose oral health status, but, you
14 know, they can certainly identify or recognize that
15 they have problems. So if it were reworded, that
16 would help.

17 On determining the need for dental
18 mouthguards, I believe they can, but perhaps that
19 should also be modified to say the need for dental
20 mouthguards for bruxism because there are other needs
21 as well that they would not be able to identify.

22 And finally, on determining the need for a

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1 particular design, that would be unreasonable to
2 expect a layperson to determine.

3 CHAIRPERSON SUZUKI: Thank you
4 Dr. Demko.

5 DR. DEMKO: Diagnosing of oral health
6 status is by definition something only a professional
7 can do. Determining the need for a dental guard
8 against the damage from bruxism, in an acute case,
9 yes.

10 I think where Dr. O'Brien goes is when we
11 look at the teeth as Dr. Mehta said. What we see is
12 historical. We don't know if the tooth damage that's
13 there was done 20 years ago or whether it was done in
14 the last week. So normally patients who come in and
15 request guards are going to be the people that are
16 aware that they have an acute problem now.

17 When we as dentists put guards in patients
18 who have a history of bruxism, it's sometimes
19 unnecessary that they be there because the patient is
20 no longer bruxing.

21 My concern is, number one, most dentists
22 don't know what guard to use. they use whatever they

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1 were taught in school. They use whatever the latest
2 sales rep. has brought in and said, "I use this one."

3 And so they use what's out there and whatever has
4 been their success rate.

5 So it is up to us as a panel to come up
6 with something that our best background and success
7 would tell us we should use, that in the future
8 bruxism is a medical disorder. It is now ICD-9
9 diagnosed as a sleep disorder; that we have to look at
10 the damage we see on the teeth is a symptom as
11 insomnia is of a sleep disorder. It doesn't mean it's
12 the disease itself. The cause of that tooth movement
13 as research goes on is going to change with the influx
14 of research in this area.

15 So that we have to take into account that
16 what we see on the teeth is simply a symptom of a
17 systemic possibly or central nervous system disease,
18 sympathetic responses to sleep disorders, and that as
19 we learn more about the overall disease and not just
20 look at the symptom, we have to understand that this
21 does need to be controlled by the FDA.

22 CHAIRPERSON SUZUKI: Okay. Thank you.

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1 Dr. Suzuki -- yes, Dr. Cochran.

2 DR. COCHRAN: I would like to make a point
3 here, and that is that when we talk about the second
4 bullet, which is determining the need for a
5 mouthguard, one of the things we haven't talked about
6 here and I feel compelled to as a periodontist disease
7 is that there's a relationship between periodontal
8 disease, most of us feel, and the occlusion in some
9 ways or another.

10 What that relationship is exactly, we
11 don't always know what that is. A lot of patients
12 certainly don't realize that they have periodontal
13 disease, for one. In a lot of cases, particularly in
14 females, maxillary premolars will have a lot of
15 mobility associated with those teeth.

16 So in the treatment of those oral
17 conditions usually some sort of occlusal therapy,
18 whether it be a NightGuard or some other type of
19 occlusal adjustment or something, there is a
20 relationship there. So many patients aren't going to
21 realize that, one, they even have periodontal disease,
22 but secondly that they may benefit from the use of

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1 some sort of occlusal appliance.

2 And so I would think in the labeling that
3 was passed out one of the things that we might want to
4 add to that instruction is the statement that
5 mouthguards may be needed for reasons that are not
6 obvious to the patient, and I don't think we can lose
7 sight of the fact that this is an integral part of
8 some periodontal therapy.

9 CHAIRPERSON SUZUKI: Okay, but to
10 summarize at least the majority of the panel feels
11 that the layperson is not in the position to diagnose
12 their oral health status. The layperson can, in fact,
13 determine their need for a dental mouthguard, and the
14 layperson cannot determine the design of a specific
15 NightGuard.

16 DR. COCHRAN: A point of clarification on
17 that second bullet. That was for bruxism.

18 CHAIRPERSON SUZUKI: Yes, for bruxism and
19 teeth grinding.

20 Okay. Question No. 3: is OTC use
21 appropriate for all designs of dental mouthguards?

22 I'll begin to poll the panel again to

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1 answer this question. Dr. Cochran.

2 DR. COCHRAN: I would answer no.

3 CHAIRPERSON SUZUKI: Dr. O'Brien.

4 DR. O'BRIEN: No.

5 CHAIRPERSON SUZUKI: Dr. Zero.

6 DR. ZERO: No.

7 CHAIRPERSON SUZUKI: Dr. Zuniga.

8 DR. ZUNIGA: No.

9 CHAIRPERSON SUZUKI: Ms. Howe.

10 MS. HOWE: I'd like to pass on that right
11 now. Thank you.

12 CHAIRPERSON SUZUKI: Okay. Mr. Schechter.

13 MR. SCHECHTER: I don't have an opinion.

14 CHAIRPERSON SUZUKI: Okay. Dr. Bakland.

15 DR. BAKLAND: No.

16 CHAIRPERSON SUZUKI: Dr. Demko.

17 DR. DEMKO: No.

18 CHAIRPERSON SUZUKI: Are any of them
19 appropriate for OTC use? The question is: is OTC use
20 appropriate for all designs of NightGuards? Are any
21 appropriate?

22 DR. O'BRIEN: I would make a comment in

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1 that many people have mouthguards, including myself,
2 and one of the problems with mouthguards is loss, if
3 you lost your mouthguard while you're traveling or
4 something like that, which is very common, I
5 understand. I guard mine very carefully.

6 If there was one of these designs that was
7 a temporary one that you could use until you get home
8 where you have your dentist make another one, that
9 would be certainly useful, but I haven't heard enough
10 about that.

11 Is there one of these designs that would
12 be a temporary type that would be useful between
13 mouthguards or if they're lost?

14 CHAIRPERSON SUZUKI: So as a provisional
15 use until you get back to your dentist.

16 DR. O'BRIEN: Provisional would be.

17 DR. COCHRAN: For \$25 you can get one.

18 DR. O'BRIEN: What's that?

19 DR. COCHRAN: For \$25 you can get one.

20 CHAIRPERSON SUZUKI: Ms. Howe.

21 MS. HOWE: Again, I'd like to bring up our
22 need to be evidence based, and there has been no

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1 evidence to say that anything that is currently on the
2 marketplace has done any damage.

3 CHAIRPERSON SUZUKI: Okay. Is that enough
4 for FDA or would you like further clarification?

5 PARTICIPANT: That's good.

6 CHAIRPERSON SUZUKI: Thank you.

7 We may have time for one more question.
8 Of the dental mouthguard designs supported for OTC
9 use, please recommend the following regarding the
10 device's labeling.

11 Those questions are listed on the screen
12 and we can poll the panel and determine them one at a
13 time.

14 Dr. Cochran.

15 DR. COCHRAN: I'm not sure what the
16 question is.

17 CHAIRPERSON SUZUKI: What information
18 should be provided to help the lay user determine the
19 need for the device? What information should be
20 provided to help the lay user ascertain the proper
21 fix? Select an appropriate design or be aware of the
22 contraindications.

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1 DR. COCHRAN: -- question please.

2 DR. COCHRAN: Okay. Dr. Bakland.

3 DR. BAKLAND: This would refer
4 specifically to the labeling of the device as I
5 understand it, correct?

6 CHAIRPERSON SUZUKI: Yes.

7 DR. BAKLAND: Okay. Then that might help.

8 CHAIRPERSON SUZUKI: Okay. This is with
9 respect to the labeling.

10 DR. COCHRAN: I guess you're asking my
11 view on this.

12 CHAIRPERSON SUZUKI: This is Dr. Cochran.

13 DR. COCHRAN: Yeah. I would think that
14 what we have before us that was passed out for the "do
15 not use," the "ask dentist," and the "stop use" are
16 appropriate, but I would make the addition that
17 mouthguards may be needed for other reasons that the
18 patient is unaware of.

19 CHAIRPERSON SUZUKI: Okay. Proper fit of
20 the device?

21 DR. COCHRAN: Yes, if the product falls
22 out. So I think that's related.

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1 DR. DEMKO: Well, that speaks to
2 retention, it doesn't necessarily speak to fit.

3 DR. COCHRAN: Right, right.

4 DR. DEMKO: It may not cover the distal
5 molars and you can get extrusion of those teeth.

6 DR. COCHRAN: Right.

7 CHAIRPERSON SUZUKI: The Chair and the
8 secretary don't have copies of the document. Are
9 there any more?

10 Okay. So, Dr. Cochran, you were referring
11 to this document.

12 DR. COCHRAN: Yes.

13 PARTICIPANT: Those were what I had given
14 you, Mr. Chairman, at the end of the morning.

15 CHAIRPERSON SUZUKI: Yes, and the Chair
16 and the secretary passed it out to everybody else.

17 Okay. Dr. O'Brien, your comment? What
18 information should be provided to help the lay user?
19 Are you going to refer to this document also?

20 DR. O'BRIEN: Yes.

21 CHAIRPERSON SUZUKI: Okay. Do you agree
22 with Dr. Cochran's comments then?

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1 DR. O'BRIEN: What does it have to do with
2 this document?

3 CHAIRPERSON SUZUKI: When not to use it,
4 be aware of the contraindications.

5 DR. O'BRIEN: Yes, yes, should be aware of
6 that, yes.

7 CHAIRPERSON SUZUKI: Okay. Dr. Zero.

8 DR. ZERO: Yeah, i think this covers most
9 of the issues in question.

10 CHAIRPERSON SUZUKI: Okay. Dr. Zuniga.

11 DR. ZUNIGA: I would like to just point
12 out a couple of things regarding certainly the proper
13 fit of the device. I think it should inform the
14 individual if the device causes pain, wearing the
15 device causes pain, or causes pressure. I think you
16 have to clarify individuals will describe pain and
17 pressure differently and they may indicate pending
18 tooth movement, those types of things.

19 Under select appropriate design, I think
20 that there should be clarification that the device
21 should cover the entire teeth in the arch, whatever
22 arch is being covered for the reasons of orthodontic

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1 movements, and not to use the device if that changes
2 in time because I assume these devices will change
3 over time because of their physical properties. So I
4 don't know.

5 CHAIRPERSON SUZUKI: Okay.

6 DR. ZERO: And then I agree with Dr.
7 Cochran that the addition under aware of
8 contraindications include periodontal disorders or
9 other.

10 CHAIRPERSON SUZUKI: Okay. Thank you.

11 Any other comments or questions on this
12 question? Yes, Dr. Bakland.

13 DR. BAKLAND: My support for this would be
14 that the label should clearly spell out all four of
15 these areas, and that the recommendation by I believe
16 it's Dental Concepts on the warning should be
17 included.

18 CHAIRPERSON SUZUKI: Okay. Dr. Demko.

19 DR. DEMKO: And I'm going back to my
20 original labeling that I think there should be a
21 comment made that bruxism is a medical disorder and
22 may indicate a more serious disorder.

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1 CHAIRPERSON SUZUKI: Okay. Any other
2 discussion?

3 So under contraindications we wanted to
4 add if the device causes pain or tooth movement I
5 believe was the word used, and if there are any other
6 medical complications to be identified, too; is that
7 correct, Dr. Demko?

8 DR. DEMKO: Yes.

9 CHAIRPERSON SUZUKI: Okay, and any other
10 questions or comments from the panel?

11 DR. ZERO: Just on the third point, select
12 an appropriate design, I don't see how we're getting
13 at that question.

14 CHAIRPERSON SUZUKI: Okay. Did FDA have a
15 question on appropriate design? Because I believe
16 that in the question above we indicated that OTC is
17 not appropriate for all designs.

18 MR. MULRY: I think we were kind of
19 looking to have some input on full versus partial
20 coverage and then soft versus hard, whether there
21 would be any differentiation in OTC use for one versus
22 the other.

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1 CHAIRPERSON SUZUKI: Okay. Would the
2 panel members like to comment on that question, more
3 specific question, on full versus partial coverage,
4 hard versus soft? Dr. Cochran.

5 DR. COCHRAN: If you want me to go first,
6 I would say full should be full coverage, and I don't
7 think if it matters if it's soft or hard as long as
8 these labeling instructions go with it.

9 CHAIRPERSON SUZUKI: Okay. Any other
10 comments or questions?

11 (No response.0

12 CHAIRPERSON SUZUKI: Okay. I believe that
13 summarized it. Is that okay?

14 Now, the question is should we do Question
15 5. Okay. Let's do Question 5 and then we'll recess
16 for lunch.

17 Do you believe a clinical study, actual
18 home use study is needed to support an OTC indication
19 for dental mouthguards? If not, please discuss your
20 reasons. If so, please discuss the following aspects
21 of the study needed for study design endpoints,
22 adverse events that would be considered significant.

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1 Okay. Dr. Cochran.

2 DR. COCHRAN: I don't think we need a
3 study. We were talking about evidence based. There's
4 no evidence that it's particularly effective or
5 ineffective. The patient does the self-diagnosis, as
6 was pointed out, and if it's not working, the patient
7 is not going to use it.

8 So in my view I don't think you really
9 need a study.

10 CHAIRPERSON SUZUKI: Okay. Dr. O'Brien.

11 DR. O'BRIEN: A study would be useful to
12 determine whether or not the patient following the
13 directions actually obtains a good fit. In other
14 study, researchers would assess the level of fit.

15 Also in terms of feedback from the patient
16 in terms of whether they continue to use the
17 mouthguard or have any particular problems with them,
18 and to see if there's any adverse effects by the use
19 of the mouthguard, by questioning the patient, also
20 by examination.

21 CHAIRPERSON SUZUKI: Okay. Dr. Zero.

22 DR. ZERO: Again, it's very hard for a

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1 clinical researcher to say that you don't need a
2 study, but I would agree that in this case there isn't
3 a need. I think there is some built in market
4 surveillance that would occur, as would any FDA
5 adverse event. So I'm okay without a study.

6 CHAIRPERSON SUZUKI: Okay. Dr. Zuniga.

7 DR. ZUNIGA: I would say no if the
8 indications were bruxism and tooth grinding only. I
9 would say yes if there was compelling evidence that
10 there's significant adverse events, such as suggested
11 by Respironics, but I'm not sure that it was
12 compelling today.

13 I would say yes if the indications were
14 for change and short-term pain relief was added. Then
15 I think you should be evidence based for an OTC use.

16 CHAIRPERSON SUZUKI: Okay. Thank you.

17 Did you want to make a comment?

18 DR. DEMKO: To Dr. Zuniga.

19 CHAIRPERSON SUZUKI: Okay.

20 DR. DEMKO: Basically on what --

21 CHAIRPERSON SUZUKI: This is Dr. Demko.

22 DR. DEMKO: Dr. Demko.

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1 -- what Respironics presented was looking
2 at a pilot study done by Eve Gagnan, who is one of
3 Gene Levigne's graduate students, and talking about
4 how patients with obstructive sleep apnea could
5 potentially get worse. None of the numbers were
6 statistically significant. It was a very small number
7 of patients, which is why if you read this very
8 difficult to read, quite how they stated it here.

9 Secondly, feedback from Dr. Mehta quoting
10 a different study, those are different people. Those
11 people that he quoted in the May 2004 study did not
12 have sleep apnea, whereas the other ones did, and you
13 have to take into account that patients wearing
14 appliances for obstructive sleep apnea, published
15 literature shows that ten to 15 percent of those
16 people wearing a mandibular repositioning device also
17 get worse.

18 So because we're not treating a disease
19 here, we're treating symptoms of a disease, I think
20 that we're arguing apples and oranges.

21 CHAIRPERSON SUZUKI: Okay. The industry
22 representations, Ms. Howe.

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1 MS. HOWE: I'd say there's no need for any
2 clinical research considering these products have been
3 on the markets for years, sold to millions of people
4 with no negative responses.

5 CHAIRPERSON SUZUKI: Okay. Mr. Schechter.

6 MR. SCHECHTER: I think now study would be
7 needed.

8 CHAIRPERSON SUZUKI: Okay. Dr. Bakland?

9 DR. BAKLAND: In the absence of a problem,
10 there doesn't seem to be any need for any study.

11 CHAIRPERSON SUZUKI: Okay, and Dr. Demko.

12 DR. DEMKO: I agree there's no need for a
13 study.

14 CHAIRPERSON SUZUKI: Okay. To summarize
15 for the FDA, no study is currently needed with the
16 indications for bruxism and tooth grinding, and we
17 will rely on market surveillance and FDA adverse
18 effects to be reported.

19 Okay. This concludes our program. I wish
20 to thank the members of the panel and the speakers for
21 their presentation and participation of this meeting.
22 Before we adjourn, the FDA would like to make a brief

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1 presentation.

2 Dr. Runner.

3 DR. RUNNER: Thank you.

4 We have several panel members who this
5 will be their final panel meeting, including our
6 distinguished Chair, and we would like to offer you
7 some appreciation for your hard work over the years,
8 and it's a small government appreciation. So for Dr.
9 Jon Suzuki, who has been our Chair for the last
10 several years, thank you very much.

11 (Applause.)

12 DR. RUNNER: Also leaving our panel this
13 year is Dr. David Cochran, and we also appreciate your
14 work on the Dental Products Panel. Thank you.

15 (Applause.)

16 DR. RUNNER: Also our consumer
17 representative, Ms. Elizabeth Howe, this is her last
18 panel meeting as well, and thank you very much for
19 your participation.

20 (Applause.)

21 DR. RUNNER: And final, Mr. Daniel
22 Schechter, our industry representative, this is also

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1 his final meeting. Thank you very much for your hard
2 work and participation.

3 (Applause.)

4 CHAIRPERSON SUZUKI: Thank you, Dr.
5 Runner.

6 Since there is no further business, I
7 would like to adjourn this meeting of the Dental
8 Products Panel.

9 Thank you.

10 (Whereupon, at 11:37 a.m., the above-
11 referenced meeting was concluded.)

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